

EPA Pesticide Petition No. 8F4996

REFERENCE REQUESTS - FEDERAL RECORDS CENTERS	NOTE: Use a separate form for each request.
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SECTION I - TO BE COMPLETED BY REQUESTING AGENCY

ACCESSION NO.	AGENCY BOX NUMBER	RECORDS CENTER LOCATION
412060017	18/36	

DESCRIPTION OF RECORD(S) OR INFORMATION REQUESTED

[] BOX

[X] FOLDER (include file number and title)— 638120 8F4996

REMARKS requested for Smith, Kimberly

NATURE OF SERVICE

[] FURNISH COPY OF RECORD (S) ONLY	[] PERMANENT WITHDRAWAL	[X] TEMPORARY LOAN OF RECORD(S)
[] REVIEW	[] OTHER (Specify)	

SECTION II - FOR USE BY RECORDS CENTER

<div><div>[] RECORDS NOT IN CENTER CUSTODY</div><div>[] WRONG ACCESSION NUMBER-PLEASE RECHECK</div><div>[] WRONG BOX NUMBER-PLEASE RECHECK</div><div>[] WRONG CENTER LOCATION-PLEASE RECHECK</div><div>[] ADDITIONAL INFORMATION REQUIRED TO IDENTIFY RECORDS REQUESTED</div><div>[] MISSING (Neither record(s), information nor charge card found in container(s) specified)</div><div>[] RECORDS DESTROYED</div><div>[] RECORDS PREVIOUSLY CHARGED OUT TO (Name, agency and date):</div></div>	REMARKS			
	Returned			
		DATE	SERVICE	TIME REQUIRED

SECTION III - TO BE COMPLETED BY REQUESTING AGENCY

NAME OF REQUESTOR Sylvia Dillard or Angela G. Smith	TELEPHONE NO. 703-605-0718 240-347-2081	DATE	RECEIPT OF RECORDS	
NAME AND ADDRESS OF AGENCY	US Environmental Protection Agency 2777 South Crystal Drive Arlington, VA 22202 Mail code: 7502P		Requestor please sign, date and return this form, for file item(s) listed above, ONLY if the block to the right has been checked by the Records Center. []	
			SIGNATURE	DATE

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REGISTRANT/COMPANY NAME:

Biosafe

Fast Track: Yes ☐ No ☐

Reviewer Diana Hudson

Assigned by LH

EPA REG./FILE SYMBOL 8F4996

ACTION CODE 232

[Note: If Fast Track, you may
need to change Reviewer's
Name in PRAT.]

(New A.I./EUP'S/Tolerances: Yes ☐ No ☐)

DATE OF APPLICATION 9-5-2000

EPA RECEIVED DATE 9.7.2000

PM RECEIVED DATE 8.25.01

SUBMISSION BARCODE 5602557

ASSIGNED IN PRAT: Yes ☒ No ☐

COMPLETED BY T. Betha DATE 8/29/01

LOGGED IN BRATS: Yes ☐ No ☐ DATE _____

* Diana: As we discussed
attached is the petition
to amend the existing
tol. exemp. for which you
currently have an action.
This needs immediate
attention to publish, see
me. Linda
* Transfer jacket to you

FINAL ACTION

RESPONSE CODE: 40

RESPONSE DATE: 6/20/02
09-12-01

MOS: _____ (1) Cite All
_____ (4) Not Applicable
_____ (8) Selective

CRP Yes ☐ No ☐

Restricted Use: Yes ☐ No ☐

Manufacturing Use: Yes ☐ No ☐

Exclusive Use: Yes ☐ No ☐

OPPTS-41R Staff

***** -IND. XMT JOURNAL- ***** DATE JUN-07-2002 ***** TIME 14:33 *****

DATE/TIME = JUN-07-2002 14:29
JOURNAL No. = 29
COMM.RESULT = OK
PAGE(S) = 007/007
DURATION = 00:02'36
FILE No. = 145
MODE = MEMORY TRANSMISSION
DESTINATION = 92028720745
RECEIVED ID = / TSG
RESOLUTION = STD

-EPA/OPP/BPPD -

***** -EPA/OPP/BPPD - ***** 703 305 0118- *****



**Biopesticides and
Pollution Prevention
Division**

FAX

June 7, 2002

Page: 7 (including cover page)

To: Amy Roberts
Regulatory Consulting for BioSafe Systems
Office: (202) 828-8964
Fax: (202) 872-0745

From: S. Diana Hudson
US Environmental Protection Agency
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division (7511C)
1200 Pennsylvania Ave NW, Washington, DC 20460
703-308-8713 (*phone*) 703-308-7026 (*fax*)
email: hudson.diana@epa.gov

Message:

As discussed in the meeting on yesterday, here's an advanced copy of the revised Federal Register; please call me you have any questions.

Thank you.

MAR - 4 2002

Attached You Will Find the Index of Documents Submitted Under Docket #301217

*Hydrogen Peroxide, an Amendment to an
Exemption from the Requirement of a
License*

*When Comments are Received, A Copy of the Comments Will be Enclosed.

Contact the Docket Staff if There are any Questions: (703) 305-5805

*Comments Enclosed: (Yes)___ (No)___✓

Hydrogen Peroxide, An Amendment to
an Exemption from the Requirement of
a Tolerance
OPP #301217

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0001	02/28/02	Hudson	EPA	Hydrogen Peroxide An Amendment to an Exemption from the Requirement of a Tolerance	9	A
0002	10/19/98	Toghrol	EPA	"Me Too" Registration of Oxide Broad Spectrum Algicide/Fungici de- Containing 27.18% Hydrogen Peroxide.....CBI has been Redacted - CBI Version Avail	0	A
0003	06/17/97	Roy	Solvay Interlox	Measurement of Physico-Chemical Properties (MRID #44302-01 (Affirmation Re'qrd)	22	B
0004	07/02/97	Sibinovic	BioSafe Systems, Inc.	Product Chemistry - ZeroTol - Broad Spectrum Algeacide, Fungicide Affirmation Re'qrd "B" Section pgs. 1-37, FOIA Re'qrd "C" Section pgs 38-41	41	B/C
0005	/ /	Sibinovic	BioSafe Systems, Inc.	Product Chemistry - Zero Tolerance Algeacide, Fungicide, Disinfectant	21	B

(MRID
#441160-01)
(Affirmation
Re'qrd)

Hydrogen Peroxide, An Amendment to
an Exemption from the Requirement of
a Tolerance
OPP #301217

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0006	08/06/96	Willis	Case Consulting Labs, Inc.	Preliminary Analysis and Precision and Accuracy of Analytical Method Used to Validate Certified Limits (MRID #441160-02) (Affirmation Re'qrd)	12	B
0007	08/06/96	Willis	Case Consulting Labs, Inc.	Physical and Chemical Characteristics of Zero Tolerance (MRID #441160-03) (Affirmation Re'qrd)	13	B
0008	/ /	Sibinovic	Biosafe Systems, Inc.	Haskell Laboratory - Review of Hydrogen Peroxide Toxicology (MRID #441160-04) (Affirmation Re'qrd)	117	B
0009	/ /	Sibinovic	Biosafe Systems, Inc.	JACC Report #22 - Hydrogen Peroxide (MRID #44160-05) (Affirmation Re'qrd)	141	B
0010	09/05/00	Roberts	Technology Sciences Group, Inc.	Petition for an Amendment to the Exemption from the Requirement of a Tolerance for Residue of Products Containing the Active	0	

IngredientHydrog
en.....

Page No. 3
03/04/02

Hydrogen Peroxide, An Amendment to
an Exemption from the Requirement of
a Tolerance
OPP #301217

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0011	09/05/00	Roberts	Technology Sceinces Group, Inc.	Tolerances Petition Fees	3	A
0012	11/01/01	Hollis	EPA	Notice of Filing a Pesticide to Establish a Tolerance for a Certain Pesticide Chemical in or on Food (FR Notice)	6	A

*** Total ***

385

(Some Material May Contain Confidential Business Information)

Index of Documents Submitted

Hydrogen Peroxide: Exemption from the Requirement of a Tolerance

OPP-301217; FRL-6822-7

	<u>Title</u>	<u>Author</u>	<u>Date</u>
1.	Review of Product Chemistry and Toxicology Studies	Freshteh Toghrol	10/19/98
2.	Data Submissions: MRID #443402-01 MRID #443142-01 MRID #441160-01 MRID #441160-02 MRID #441160-03 MRID #441160-04 MRID #441160-05		
3.	Information to support an amendment to the exemption from the requirement of a tolerance for residues of products containing the active ingredient Hydrogen Peroxide (40 CFR Part 180.1197)	Amy Roberts	9/5/00
4.	Copy of a Tolerance Petition Fees	Amy Roberts	9/5/00
5.	Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food	Diana Hudson/ Linda Hollis	11/1/01
6.	Hydrogen Peroxide: Exemption from the Requirement of a Tolerance; Final Rule	Diana Hudson	2/20/02



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDE PROGRAMS

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PUBLIC RECORD CERTIFICATION

This is to certify that the materials assembled as the official public rulemaking record for the
Federal Register docket identified as OPP-301217; Hydrogen Peroxide; Exemption From The
(Insert Docket # and Title)
Requirement of a Tolerance: Final Rule

has been reviewed by the Public Information and Records Integrity Branch.

The information is complete, and has been assembled in an useable form to
support the document being published in the Federal Register.

Cross-Reference File: _____
(Insert Docket # and Title of Cross-Reference File)

Dated: 2-8-02

Diana Hudson
Program Office

Sharon McRute
Public Information and Records
Integrity Branch (OPP Docket)

Index of Documents Submitted

**Hydrogen Peroxide: Exemption from the Requirement of a
Tolerance**

OPP-301217; FRL-6822-7

	<u>Title</u>	<u>Author</u>	<u>Date</u>
1.	Information to support an amendment to the exemption from the requirement of a tolerance for residues of products containing the active ingredient Hydrogen Peroxide (40 CFR Part 180.1197)	Amy Roberts	9/5/00
2.	Copy of a Tolerance Petition Fees	Amy Roberts	9/5/00
3.	NOT		
3.4	Hydrogen Peroxide: Exemption from the Requirement of a Tolerance; Final Rule	Diana Hudson	Pending
5.	DATA		

*Hydrogen peroxide
tol. exemp. Amend to add
all post harvest
commodities*

FILE NAME: Hydrogen peroxide petition.wpd (9/05/00)

*Diana:
Submit to OFR*

**EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY
NOTICE OF FILING TEMPLATE FOR PESTICIDE PETITIONS PUBLISHED IN THE
FEDERAL REGISTER**

EPA Biopesticides and Pollution Prevention Division contact: [Anne Ball (703) 308-8717]

INSTRUCTIONS: Use this template in preparing your notice of filing for your company's pesticide petition. In cases where the outline element does not apply, insert "NA-Remove" and maintain the outline. The comment balloons appearing in the left margin contain Government Printing Office (GPO) typesetting codes which expedite the **Federal Register** (FR) publication process at EPA for the FR document containing your company's pesticide petition. In the template, do not remove or alter the comment balloons; change the margins, font, or format; or use the WordPerfect comment function. Follow the instructions that appear italicized, color coded, and bracketed.

SUBMISSION: E-mail the completed template to: [ball.anne@epa.gov].

TEMPLATE:

EPA has received a pesticide petition [insert petition number] from [BioSafe Systems, 80 Commerce Street, Glastonbury, CT 06033], proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide [Hydrogen peroxide].

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, [BioSafe Systems] has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [BioSafe Systems] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. [BioSafe Systems] Petition Summary

[Insert petition number]

FILE NAME: Hydrogen peroxide petition.wpd (9/05/00)

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I. [BioSafe Systems] Petition Summary

[Insert petition number]

A. Product name and Proposed Use Practices

[Hydrogen peroxide is for use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites. BioSafe Systems maintains two registrations for 27.00% hydrogen peroxide end-use products, ZeroTol® (EPA Reg. No. 70299-1) and Oxidate® (EPA Reg. No. 70299-2), for these uses.]

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues.

[Hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which is of toxicological concern.]

2. Magnitude of residue at the time of harvest and method used to determine the residue.

[NA-Remove]

3. A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.

[An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.]

C. Mammalian Toxicological Profile

[Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2000 ppm). Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR Part 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).]

D. Aggregate Exposure

1. Dietary exposure.

i. Food.

[For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR Part 184.1366).]

ii. Drinking water.

[At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.]

2. Non-dietary exposure.

[There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.]

E. Cumulative Exposure

[Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.]

F. Safety Determination to the General US Population, and Infants and Children

[Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at $\leq 1\%$, will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.]

G. Effects on the Immune and Endocrine Systems

[There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.]

H. Existing Tolerances

[40 CFR Part 180.1197 - An exemption from the requirement of a tolerance is established for residues of **hydrogen peroxide** in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algicide, fungicide and bactericide.]

I. International Tolerances

[There is no Codex Alimentarius Commission Maximum Residue Level (MRL) for hydrogen peroxide.]

JACKETS (Fileroom Document Tracking System)
Requested Jackets Report (New Requests)

08/02/01
10:43:38
LVISSSE

Requested by : KING, RICHARD

Barcode : 020915

Agency : EPA Office : OPPTS Program : OPP
Division : BPPD Branch : BPB Section :

Requested on 08/02/01 at 10:40

Jacket Barcode	Regulatory Case File #	Vol/Total	Location	Status
000638120	8F4996	1 / 1	50 / A / 03 / 3	Pending

Total # of jackets requested : 1

Completed: RS Date: 08-2 Time: 11:04

KING, RICHARD

Linda Hollis

08/25/2001 05:01 PM

To: Diana Hudson/DC/USEPA/US@EPA

cc:

Subject: Fw: Electronic Notice of Filing for Hydrogen Peroxide Exemption Amendment

this is the petition.

----- Forwarded by Linda Hollis/DC/USEPA/US on 08/25/2001 05:01 PM -----



Amy Roberts
<aroberts@tsgusa.com>
m>

08/01/2001 01:20 PM

To: Linda Hollis/DC/USEPA/US@EPA

cc:

Subject: Fw: Electronic Notice of Filing for Hydrogen Peroxide Exemption Amendment

Linda - Here it is again. This is what I had also previously emailed to Mike. If you need it, I can fax or mail you a hard copy of the original petition, cover letter and fee. In addition, there is a corresponding label amendment for Oxidate (70299-2) that was submitted late April 2001, to add all multiple postharvest commodities to the label. I think the label amendment is with Raderrio?

Regards, Amy Roberts

----- Original Message -----

From: Amy Roberts

To: Linda Hollis

Cc: Rob Larose

Sent: Tuesday, July 03, 2001 5:11 PM

Subject: Electronic Notice of Filing for Hydrogen Peroxide Exemption Amendment

Linda - Attached you will find the electronic notice of filing for the hydrogen peroxide tolerance exemption amendment that was filed September 5, 2000 by BioSafe Systems. This amendment is to add all postharvest agricultural commodities to the exemption, instead of just postharvest potatoes as it is listed now. Refer to my previous email for the status of this action. Regards, Amy Roberts

PS - Note, this is separate action from the Sodium Percarbonate active ingredient issue.

Hydrogen peroxide petition.w

FILE NAME: Hydrogen peroxide petition.wpd (9/05/00)

**EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION
COMPANY NOTICE OF FILING TEMPLATE FOR PESTICIDE
PETITIONS PUBLISHED IN THE FEDERAL REGISTER**

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U.S. Environmental Protection Agency

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Hydrogen Peroxide; An Amendment to an Exemption From the Requirement of a Tolerance; Technical Correction

[Federal Register: June 20, 2002 (Volume 67, Number 119)]

[Rules and Regulations]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0042; FRL-6835-3]

RIN 2070-AB78

Hydrogen Peroxide; An Amendment to an Exemption From the Requirement of a Tolerance; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: In the Federal Register of February 28, 2002, EPA issued a revised exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide. In the SUMMARY and the codified text, a phrase was inadvertently omitted. This document corrects those errors.

DATES: This document is effective June 20, 2002.

FOR FURTHER INFORMATION CONTACT: By mail: Diana Hudson, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number (703) 308-8713; and e-mail address: hudson.diana@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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2. In person. The Agency has established an official record for this action under docket control number OPP-2002-0042. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background

A. What Does This Technical Correction Do?

In the Federal Register of February 28, 2002 (67 FR 9214) (FRL-6822-7), EPA revised an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide. In the SUMMARY and the codified text, a phrase was inadvertently omitted. This document corrects those errors.

On page 9214, third column, the first sentence of the summary is corrected to read as follows: "This regulation establishes an amendment to an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide in or on all food commodities when applied/used at the rate of $\leq 1\%$ hydrogen peroxide per

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application on growing and postharvest crops.'

The codified text is corrected in the regulatory text of this document.

B. Why is This Technical Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b) (B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's technical correction final without prior proposal and opportunity for comment, because EPA is merely adding a phrase that was inadvertently omitted from the previously published final rule. EPA finds that this constitutes good cause under 5 U.S.C. 553(b) (B).

III. Regulatory Assessment Requirements

This final rule implements a technical amendment to the Code of Federal Regulations, and it does not otherwise impose or amend any requirements. As such, the Office of Management and Budget (OMB) has determined that a technical correction is not a "significant regulatory action" subject to review by OMB under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since this action does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n) (4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal

implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IV. Submission to Congress and the Comptroller General?

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 7, 2002.

Janet L. Andersen.

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180-- [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.1197 is revised to read as follows:

180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing and postharvest crops.

[FR Doc. 02-15618 Filed 6-19-02; 8:45 am]

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List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: 6/7/02

James H. Anderson

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

BILLING CODE 6560-50-S

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*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide
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[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

BILLING CODE 6560-50-S

Linda Hollis

04/15/02 02:16 PM

To: Diana Hudson/DC/USEPA/US@EPA

cc:

Subject: PDF file

----- Forwarded by Linda Hollis/DC/USEPA/US on 04/15/02 02:16 PM -----

Debbie-E Thomas

04/12/02 06:29 PM

To: Linda Hollis/DC/USEPA/US@EPA

cc:

Subject: PDF file

Linda , attached is the PDF file for the correction. The concurrence package is in the mail.



linda.pdf



Amy Roberts
<aroberts@tsgusa.com>
m>

02/28/02 10:21 AM

To: Linda Hollis/DC/USEPA/US@EPA, Diana
Hudson/DC/USEPA/US@EPA
cc:
Subject: H2O2 Final Rule

Linda - Further to my voicemail, I am very concerned about the H2O2 tolerance exemption amendment final rule that published in the FR today. The amendment is supposed to **expand** the existing H2O2 tolerance exemption amendment to include all postharvest commodities (not just postharvest potatoes), but according to the final rule, it appears to have superseded it.

Today's FR notice lists the citation as:

40 CFR 180.1197

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all postharvest food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application.

BUT, the previous tolerance exemption was:

40 CFR 180.1197

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algacide, fungicide and bactericide.

What has happened to the "in or on all food commoditieswhen applied to growing crops"!?! Is this a mistake? Has the exemption for hydrogen peroxide in or on all food commodities when applied to growing crops be deleted?

Regards, Amy



Related Material

- Other Related Documents

[Federal Register: February 28, 2002 (Volume 67, Number 40)]
[Rules and Regulations]
[Page 9214-9218]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr28fe02-17]

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[OPP-301217; FRL-6822-7]
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AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes an amendment to an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide in or on all post-harvest agricultural food commodities when applied/used at the rate of $\leq 1\%$ hydrogen peroxide per application. Biosafe Systems, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This

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regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

DATES: This regulation is effective February 28, 2002. Objections and requests for hearings, identified by docket control number OPP-301217, must be received by EPA, on or before **April 29, 2002**.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301217 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Diana Hudson, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8713; and e-mail address: hudson.diana@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

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2. In person. The Agency has established an official record for this action under docket control number OPP-301217. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the Federal Register of November 1, 2001 (66 FR 55175) (FRL-6805-7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by the FQPA (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Biosafe Systems, Inc., 80 Commerce Street, Glastonbury, CT 06033. This notice included a summary of the petition prepared by the petitioner Biosafe Systems, Inc.. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1197 be amended by

establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17%)

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hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral LD₅₀ 5,000 milligrams/kilograms (mg/kg) in rats (toxicity category III), an acute dermal LD₅₀ ≥ 10,000 mg/kg in rabbits (toxicity category IV), and an inhalation LC₅₀ of 4 milligram/liter (mg/L) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral LD₅₀ < 500 mg/kg in rats (toxicity category II), and an acute dermal LD₅₀ < 1,000 mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC₅₀ = 4 mg/L (2,000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide has no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheesemaking, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. Food. For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09-0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore, residues in or on treated post-harvest food commodities of the algacide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. Drinking water exposure. At the proposed application rates, the use of hydrogen peroxide as an algacide, fungicide, and bactericide to treat all post-harvest agricultural food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

VI. Cumulative Effects

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

VII. Determination of Safety for U.S. Population, Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses

employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all post-harvest food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VIII. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels established for residues on hydrogen peroxide.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a

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tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301217 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 29, 2002.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27).

Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Copies for the docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP-301217, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

Request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order

12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the

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development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating

the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 20, 2002.
Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1197 is revised to read as follows:

Sec. 180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all post-harvest food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application.

[FR Doc. 02-4791 Filed 2-27-02; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301217; FRL-6822-7]

RIN 2070-AB78

Hydrogen Peroxide; An Amendment to an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

*TO: Debbie Thomas
260-3884 4988*
From: Linda Hollis
Thanks Debbie!

SUMMARY: This regulation establishes an amendment to an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide in or on all ~~post-harvest agricultural~~ food commodities when applied/used at the rate of $\leq 1\%$ hydrogen peroxide per application. Biosafe Systems, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

delete
→ on growing and postharvest crops.

DATES: This regulation is effective [insert date of publication in the Federal Register]. Objections and requests for hearings, identified by docket control number OPP-301217, must be received by EPA, on or before [insert date 60 days after date of publication in the Federal Register].

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301217 in the subject line on the first page of your response.

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*on growing and
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[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

BILLING CODE 6560-50-S

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A. Dietary Exposure

1. *Food.* For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09–0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore, residues in or on treated post-harvest food commodities of the algaecide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. *Drinking water exposure.* At the proposed application rates, the use of hydrogen peroxide as an algaecide, fungicide, and bactericide to treat all post-harvest agricultural food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

VI. Cumulative Effects

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

VII. Determination of Safety for U.S. Population, Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all post-harvest food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that

there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VIII. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels established for residues on hydrogen peroxide.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301217 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary

of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Copies for the docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP-301217, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described

in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

Request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on

States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,
Agricultural commodities, Pesticides and pests, Reporting and
recordkeeping requirements.

Dated: 2/20/02

Janet L. Anderson

Director, Biopesticides and Pollution Prevention Division.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301217; FRL-6822-7]

RIN 2070-AB78

Hydrogen Peroxide; An Amendment to an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an amendment to an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide in or on all post-harvest agricultural food commodities when applied/used at the rate of $\leq 1\%$ hydrogen peroxide per application. Biosafe Systems, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

DATES: This regulation is effective [insert date of publication in the **Federal Register**]. Objections and requests for hearings, identified by docket control number OPP-301217, must be received by EPA, on or before [insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301217 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Diana Hudson, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8713; and e-mail address: hudson.diana@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket # 6

02p-0086

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301217. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of November 1, 2001 (66 FR 55175) (FRL-6805-7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by the FQPA (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Biosafe Systems, Inc., 80 Commerce Street, Glastonbury, CT 06033. This notice included a summary of the petition prepared by the petitioner Biosafe Systems, Inc.. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1197 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ milligrams/kilograms (mg/kg) in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 milligram/liter (mg/L) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral $LD_{50} < 500$ mg/kg in rats (toxicity category II), and an acute dermal $LD_{50} < 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, $LC_{50} = 4$ mg/L (2,000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide has no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheesemaking, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09–0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore, residues in or on treated post-harvest food commodities of the algaecide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. *Drinking water exposure.* At the proposed application rates, the use of hydrogen peroxide as an algaecide, fungicide, and bactericide to treat all post-harvest agricultural food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

VI. Cumulative Effects

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

VII. Determination of Safety for U.S. Population, Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all post-harvest food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that

there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VIII. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels established for residues on hydrogen peroxide.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary

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B. When Will the Agency Grant a Request for a Hearing?

Request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on

States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: 2/20/02



Director, Biopesticides and Pollution Prevention Division.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1197 is revised to read as follows:

§ 180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all ~~post-harvest~~ food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application.

[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

BILLING CODE 6560-50-S

on growing
post harvest
crops



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Sheryl Reilly, Chief
Anne Ball, RAL
Biochemical Pesticide Branch
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
1921 Jefferson Davis Highway
Arlington, VA 22202

September 5, 2000

Docket # 3

RE: Petition for an amendment to the exemption from the requirement of a tolerance for residues of products containing the active ingredient HYDROGEN PEROXIDE (40 CFR Part 180.1197)

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Dr. Reilly and Ms. Ball:

With this letter Technology Sciences Group, on behalf of BioSafe Systems (EPA Company No. 70299), hereby submits a petition for an amendment to the existing tolerance exemption to **include** all postharvest crops, rather than only postharvest potatoes, and to **delete** the specification "when applied as an algaecide, fungicide and bactericide," as is presently listed.

The present exemption at 40 CFR Part 180.1197 is as follows:

An exemption from the requirement of a tolerance is established for residues of **hydrogen peroxide** in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.

Our proposed amendment to the exemption is as follows:

An exemption from the requirement of a tolerance is established for residues of **hydrogen peroxide** in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing and **postharvest** crops.

SACRAMENTO

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Telephone 530 757-1298
Fax 530 757-1299

E-mail tsg@tsgusa.com

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Page 2 of 3
September 5, 2000

The addition of all postharvest crops is consistent with the use pattern of the product and does not pose a risk to human health or the environment, as is supported by the data referenced in this petition. The deletion of the specification "when applied as an algacide, fungicide and bactericide" is appropriate, as the current listing does not include all presently approved food uses of the active ingredient, such as antimicrobial, slimicidal, etc. Because hydrogen peroxide is diverse in its applications, it is more appropriate to not list those applications in the context of the tolerance exemption.

SAN FRANCISCO

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

This proposed amendment is in accordance with 40 CFR Part 180 and pursuant to Section 408(d)(1) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

In support of this petition, attached you will find the following information, submitted in duplicate:

- A. Summary of product chemistry;
- B. Proposed use practice;
- C. Toxicological profile;
- D. Aggregate exposure, including information on dietary exposure, drinking water exposure and non-dietary exposure;
- E. Cumulative effects;
- F. Safety determination, including information on the U.S. general population, and infants and children;
- G. Existing tolerances;
- H. Information on endocrine effects.

EPA has already reviewed information listed above and most of the summaries provided reflect the findings of Agency reviewers. The petitioner

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Page 3 of 3
September 5, 2000

agrees that the enclosed information may be published as part of the notice of filing of the petition, to be published under Section 408(d)(1), and as proposed for final regulation.

With this letter we are also requesting a **waiver of the fee for filing a petition** for an exemption from the requirement of a tolerance, for the following reasons:

- 1) Hydrogen peroxide is an already registered active ingredient with an established tolerance exemption for similar uses. The active ingredient reacts on contact and the degradation products (oxygen and water) are not of toxicological concern. Hydrogen peroxide does not pose any potential for unreasonable adverse effects to human health;
- 2) The fee for filing a petition for an exemption from the requirement of a tolerance would pose unreasonable hardship on the registrant, BioSafe Systems. BioSafe is a small, family-owned company that currently maintains two EPA registered products. At this time the fee would present undue financial strain on the company.

We have submitted the appropriate fee (\$1,700) for filing a waiver request to EPA Headquarters Accounting Operations Branch, Pittsburgh, PA, on this date (a copy is attached for reference).

Should you have any questions or comments on this petition please contact me directly.

Sincerely,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems
Direct dial (202) 828-8964; aroberts@tsgusa.com

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>

**Petition for an amendment to the exemption from the
requirement of a tolerance for residues of products
containing the active ingredient HYDROGEN PEROXIDE
(40 CFR Part 180.1197)**

September 5, 2000

Submitted by: Technology Sciences Group, Inc.
1101 17th Street, N.W., Suite 500
Washington, D.C. 20036

Submitted for: BioSafe Systems (EPA Company No. 70299)
80 Commerce Street
Glastonbury, CT 06033

SUMMARY:

This petition is for an amendment to the existing tolerance exemption to include all postharvest crops, rather than only postharvest potatoes, and to delete the specification "when applied as an algicide, fungicide and bactericide." The addition of all postharvest crops is consistent with the use pattern of the product and does not pose a risk to human health or the environment, as is supported by the data referenced in this petition. The deletion of the specification "when applied as an algicide, fungicide and bactericide" is appropriate, as the current listing does not include all presently approved food uses of the active ingredient, such as antimicrobial, slimicidal, etc. Because hydrogen peroxide is diverse in its applications, it is more appropriate to **not** list those applications in the context of the tolerance exemption.

SECTION A - SUMMARY OF PRODUCT CHEMISTRY

Product Name: ZeroTol™ Broad Spectrum Algicide/Fungicide
[27% Hydrogen Peroxide (Hydrogen Dioxide)]
[EPA Reg. No. 72099-1]

Oxidate™ Broad Spectrum Algicide/Fungicide
[27% Hydrogen Peroxide (Hydrogen Dioxide)]
[70299-2]

Active Ingredient: Hydrogen Peroxide (Hydrogen Dioxide)
CAS Number: 772-84-1
Molecular Formula: H₂O₂
Molecular Weight: 34.02

Color: Colorless
Physical State: Liquid
Odor: Moderately pungent
Boiling Point: 100°C
Specific Gravity: 1.091 at 22°C
Solubility: Soluble in water
pH: 1.05 at 25°C
Flammability: Non-flammable
Explodability: Non-explosive
Storage Stability: Unstable at 50°C for 30 days
Viscosity: 0.78 cS at 22°C
Corrosion Characteristics: Moderately corrosive

Mode of Action:

The mode of action of hydrogen peroxide is oxidation. Hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which is of toxicological concern.

Analytical Method:

An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.

History of Use:

Hydrogen peroxide is currently registered for pesticidal use as an antimicrobial for the control of bacteria, fungi and viruses. Originally registered in 1977, hydrogen peroxide products are used as disinfectants, sanitizers and sterilants in commercial, industrial and medical settings; including but not limited to, agricultural premises, dairy/food handling and food processing facilities, commercial facilities, eating establishments, reverse osmosis water systems, and critical and noncritical hospital settings. In its 1993 Reregistration Eligibility Decision on Peroxy Compounds, EPA concluded the use of hydrogen peroxide and other peroxy compounds does not pose an unreasonable risk or adverse effect to humans or the environment. Hydrogen peroxide is generally regarded as safe (GRAS) according to the Food and Drug Administration (FDA) (21 CFR Part 178) when used as a food additive and when used on food-processing equipment, utensils, and food contact articles. Hydrogen peroxide is also approved for medicinal use in hospitals and homes.

Hydrogen Peroxide for Agricultural Uses:

BioSafe System's products ZeroTol® and Oxidate® (27% hydrogen peroxide) are presently registered for the control of plant pathogenic diseases on ornamentals, turf, greenhouse surfaces, food commodities (growing crops), and postharvest potatoes. Due to the fact that hydrogen peroxide is known to occur naturally, and that there is a wide body of published literature and previously submitted safety data, for agricultural uses hydrogen peroxide was considered a reduced risk pesticide and qualified for reduced data requirements as a biochemical with the Biopesticides and Pollution Prevention Division, EPA.

Ecolab Inc. maintains registrations of hydrogen peroxide (at 11% and 14.9% active ingredient concentration by weight) for food uses as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices.

SECTION B - PROPOSED USE PRACTICE

For use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites.

SECTION C - TOXICOLOGICAL PROFILE

Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2000 ppm). Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR Part 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

SECTION D - AGGREGATE EXPOSURE

1) Dietary Exposure:

For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR Part 184.1366).

2) Drinking Water Exposure:

At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.

3) Non-Dietary Exposure:

There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.

SECTION E - CUMULATIVE EFFECTS

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

SECTION F - SAFETY DETERMINATION

Determination of Safety for the General US Population, Infants and Children:

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at $\leq 1\%$, will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

SECTION G - EXISTING TOLERANCES

US EPA Tolerance -

40 CFR Part 180.1197 - An exemption from the requirement of a tolerance is established for residues of **hydrogen peroxide** in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.

International -

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

SECTION H - INFORMATION ON ENDOCRINE EFFECTS

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

FILE COPY



WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

<sent via Certified Mail, article number 7099 3220 0008 2757 9389>

Environmental Protection Agency
 Headquarters Accounting Operations Branch
 Office of Pesticide Programs (Tolerance Fees)
 P.O. Box 360277M
 Pittsburgh, PA 15251

September 5, 2000

Docket # 4

RE: Tolerance Petition Fees

SAN FRANCISCO

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

Dear HQ Accounting Operations Branch:

With this letter Technology Sciences Group, on behalf of BioSafe Systems (EPA Company No. 70299), hereby submits the following in support of a petition for an amendment to an exemption from the requirement of a tolerance (40 CFR Part 180.1197):

- 1) Check for \$1,700 - fee for requesting a waiver of the fees for filing a petition for an exemption from the requirement of a tolerance.
- 2) Copy of the cover letter submitted with the petition; includes rational for waiver of the filing fee.

Should you have any questions or comments, please contact me directly at (202) 828-8964.

Sincerely,

Amy Plato Roberts
 Regulatory Consultant for BioSafe Systems
 Direct dial (202) 828-8964; aroberts@tsqusa.com

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

E-mail tsg@tsqusa.com<http://www.tsqusa.com>

Commercial/financial information may be entitled to confidential treatment

BioSafe Systems, EPA Company No. 70299
Technology Sciences Group Inc.
 1101 17th Street N.W., Suite 500
 Washington, DC 20036
 (202) 828-8942

FIRST UNION NATIONAL BANK
 WASHINGTON D.C.
 015-122/540
 00480

DATE	CONTROL NO.	AMOUNT
9/1/00	12049	\$1,700.00

PAY One thousand seven hundred and 00/100 dollars

TO THE
 ORDER OF

Environmental Protection Agency
 Headquarters Accounting Operations Branch
 Office of Pesticide Programs (Tolerance Fees)
 P.O. Box 360277M
 Pittsburgh, PA 15251

VOID AFTER 60 DAYS

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AUTHORIZED SIGNATURE

Security features included. Details on back.

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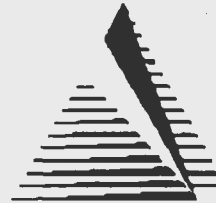
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WITHOUT PREJUDICE, ABSENCE
OF ENDORSEMENT GUARANTEED
MELLON BANK - JMCB-PGL/PA

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Technology Sciences Group Inc.
1101 17th Street, N.W., Suite 500
Washington, D.C. 20038
telephone (202) 223-4392
fax (202) 872-0745
website www.tsqusa.com



FACSIMILE TRANSMITTAL SUMMARY

Date: January 16, 2002
Addressee: Diana Hudson
Biopesticide and Pollution Prevention Division
Telephone: (703) 308-8713
Fax: (703) 308-7026
Number of Pages: seventeen (17)
Sender: Amy Plato Roberts

Dear Diana:

Per your request, attached you will find the following for the BioSafe Systems petition to amend the tolerance exemption for hydrogen peroxide:

- 1) Copy of letter and check for the tolerance petition fees (dated September 5, 2000).
I have also included a photocopy of the backside of the check, which is endorsed by EPA, verifying it was cashed.
- 2) Copy of original tolerance exemption petition (dated September 5, 2000).

If you have any questions or need further information, please do not hesitate to let me know.

Best regards,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems
Direct dial (202) 828-8964; email aroberts@tsqusa.com



Federal Register

Environmental Documents

[Federal Register: November 1, 2001 (Volume 66, Number 212)]
 [Notices]
 [Page 55175-55178]
 From the Federal Register Online via GPO Access [wais.access.gpo.gov]
 [DOCID:fr01no01-56]

✓ ENVIRONMENTAL PROTECTION AGENCY
 [PF-1047; FRL-6805-7]

Docket # 5

Notice of Filing a Pesticide Petition to Establish a Tolerance
 for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).
 ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide
 petition proposing the establishment of regulations for residues of a
 certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-must be
 received on or before December 3, 2001.

✓ ADDRESSES: Comments may be submitted by mail, electronically, or in
 person. Please follow the detailed instructions for each method as
 provided in Unit I.C. of the SUPPLEMENTARY INFORMATION. To ensure
 proper receipt by EPA, it is imperative that you identify docket
 control number PF-1046 the subject line on the first page of your
 response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides
 and Pollution Prevention Division, Registration Division (7505W),
 Office of Pesticide Programs, Environmental Protection Agency, 1200
 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703)
 308-8733; e-mail address: acierto.amelia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural
 producer, food manufacturer or pesticide manufacturer. Potentially
 affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112	Crop production Animal production
[[Page 55176]]		
	311 32532	Food manufacturing Pesticide

manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at <http://www.epa.gov/>. To access this document, on the homepage select "Laws and Regulations" " Regulation and Proposed Rules," and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the Federal Register listings at <http://www.epa.gov/fedrgstr/>.

2. In person. The Agency has established an official record for this action under docket control number PF-1046. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. Electronically. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-000. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

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List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 17, 2001.
Janet L. Anderson,
Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BioSafe Systems

PP 8F4996

EPA has received a pesticide petition 8F4996 from Biosafe Systems, 80 Commerce Street, Glastonbury, CT 06033], proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/ expansion of an existing tolerance exemption for the biochemical pesticide hydrogen peroxide in or on all postharvest agricultural food commodities at the rate of 1% hydrogen peroxide per application.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Biosafe Systems has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [Biosafe Systems] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product name and Proposed Use Practices

Hydrogen peroxide is for use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites. BioSafe Systems maintains 2 registrations for 27.00% hydrogen peroxide end-use products, ZeroTol (EPA Reg. No. 70299-1) and Oxidate (EPA Reg. No. 70299-2), for these uses.

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues. Hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which is of toxicological concern.

2. Analytical method. An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.

C. Mammalian Toxicological Profile

Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral LD₅₀ ≥5,000 mg/kg in rats (toxicity category III), an acute dermal LD₅₀ ≥10,000 mg/kg in rabbits (toxicity category IV), and an inhalation LC₅₀ of 4 milligrams per liter (mg/l) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral LD₅₀ ≥500 mg/kg in rats (toxicity category II) and an acute dermal LD₅₀ ≥1,000 mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC₅₀ is 4 mg/l (2,000 ppm). Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR Part 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

D. Aggregate Exposure

1. Dietary exposure--i. Food. For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR Part 184.1366).

ii. Drinking water. At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.

2. Non-dietary exposure. There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen

[[Page 55178]]

peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.

E. Cumulative Exposure

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

F. Safety Determination to the General U.S. Population, and Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at 1%, will not pose a dietary risk under reasonably foreseeable circumstances.

Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

G. Effects on the Immune and Endocrine Systems

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

H. Existing Tolerances

An exemption from the requirement of a tolerance (40 CFR Part 180.1197) is established for residues of hydrogen peroxide in or on all food commodities at the rate of 1% hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algicide, fungicide and bactericide.

I. International Tolerances

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

[FR Doc. 01-27469 Filed 10-31-01; 8:45 am]

BILLING CODE 6560-50-S

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Last Updated: Thursday, November 01, 2001 11:13:32

URL: <http://www.epa.gov/fedrgstr/EPA-PEST/2001/November/Day-01/p27469.htm>



[Federal Register: November 1, 2001 (Volume 66, Number 212)]
[Notices]
[Page 55175-55178]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr01no01-56]

ENVIRONMENTAL PROTECTION AGENCY
[PF-1047; FRL-6805-7]

Notice of Filing a Pesticide Petition to Establish a Tolerance
for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-must be received on or before **December 3, 2001.**

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides and Pollution Prevention Division, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8733; e-mail address: acierto.amelia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112	Crop production Animal production
[[Page 55176]]		
	311 32532	Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet homepage at <http://www.epa.gov/>. To access this document, on the homepage select "Laws and Regulations" "Regulation and Proposed Rules," and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the Federal Register listings at <http://www.epa.gov/fedrgstr/>.

2. In person. The Agency has established an official record for this action under docket control number PF-1046. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. Electronically. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-000. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under FOR FURTHER INFORMATION CONTACT.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

[[Page 55177]]

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 17, 2001.

Janet L. Anderson,
Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BioSafe Systems

EPA has received a pesticide petition 8F4996 from Biosafe Systems, 80 Commerce Street, Glastonbury, CT 06033], proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/expansion of an existing tolerance exemption for the biochemical pesticide hydrogen peroxide in or on all postharvest agricultural food commodities at the rate of 1% hydrogen peroxide per application.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Biosafe Systems has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [Biosafe Systems] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product name and Proposed Use Practices

Hydrogen peroxide is for use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites. BioSafe Systems maintains 2 registrations for 27.00% hydrogen peroxide end-use products, ZeroTol (EPA Reg. No. 70299-1) and Oxidate (EPA Reg. No. 70299-2), for these uses.

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues. Hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which is of toxicological concern.

2. Analytical method. An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.

C. Mammalian Toxicological Profile

Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral LD₅₀ ≥5,000 mg/kg in rats (toxicity category III), an acute dermal LD₅₀ ≥10,000 mg/kg in rabbits (toxicity category IV), and an inhalation LC₅₀ of 4 milligrams per liter (mg/l)

(toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral LD₅₀

≥500 mg/kg in rats (toxicity category II) and an acute dermal LD₅₀ ≥1,000 mg/kg in rabbits (toxicity category

II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC₅₀ is 4 mg/l (2,000 ppm).

Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of

≤1% hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR Part 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

D. Aggregate Exposure

1. Dietary exposure--i. Food. For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR Part 184.1366).

ii. Drinking water. At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.

2. Non-dietary exposure. There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen

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peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.

E. Cumulative Exposure

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

F. Safety Determination to the General U.S. Population, and Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at 1%, will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new

data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

G. Effects on the Immune and Endocrine Systems

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

H. Existing Tolerances

An exemption from the requirement of a tolerance (40 CFR Part 180.1197) is established for residues of hydrogen peroxide in or on all food commodities at the rate of 1% hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.

I. International Tolerances

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.
[FR Doc. 01-27469 Filed 10-31-01; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1046; FRL-6805-7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-1046 must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides and Pollution Prevention Division, (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8733; e-mail address: hollis.linda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

CONCURRENCES							
SYMBOL	7104	7104	7511C	7511C			
SURNAME	Hollis	D. Thomas	D. Hudson	Hollis			
DATE	10/4/01	10/4/01	10/9/01	10-11-01			

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" "Regulation and Proposed Rules," and then look up the entry for this document under the "**Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-1046. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services

Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-1046. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: 10-17-01

James L. Anderson

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BioSafe Systems

PP 8F4996

EPA has received a pesticide petition 8F4996 from Biosafe Systems, 80 Commerce Street, Glastonbury, CT 06033, proposing pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/expansion of an existing tolerance exemption for the biochemical pesticide hydrogen peroxide in or on all postharvest agricultural food commodities at the rate of 1% hydrogen peroxide per application. ✓ ≤ 1/1.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Biosafe Systems has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Biosafe Systems and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. duplicate paragraph

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, BioSafe Systems has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by BioSafe Systems and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Hydrogen peroxide is for use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites. BioSafe Systems maintains 2 registrations for 27.00% hydrogen peroxide end-use products, ZeroTol (EPA Reg. No. 70299-1) and Oxidate (EPA Reg. No. 70299-2), for these uses.

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues. Hydrogen peroxide reacts on contact with a surface on which it is applied, and

rapidly degrades to oxygen and water, neither of which is of toxicological concern.

2. *Analytical method.* An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.

C. Mammalian Toxicological Profile

Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ milligrams/kilograms (mg/kg) in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 milligrams per liter (mg/L) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/L (2,000 ppm). Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. A reference dose (RfD) (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

ii. *Drinking water*. At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.

2. *Non-dietary exposure*. There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.

E. Cumulative Exposure

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

F. Safety Determination to the General U.S. Population, and Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at $\leq 1\%$, will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low

concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

G. Effects on the Immune and Endocrine Systems

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

H. Existing Tolerances

An exemption from the requirement of a tolerance (40 CFR 180.1197) is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide, and bactericide.

I. International Tolerances

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

[FR Doc. 01-????? Filed ??-??ndash;01; 8:45 am]

BILLING CODE 6560-50-S

ROUTING & TRANSMITTAL SLIP

October 22, 2001

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Jean Gillis, FR Staff, Rm. G-304 NE Mall		
2.		
3.		
4.		
5.		

Action	File	Note And Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	X Signature
Coordination	Justify	

MARKS

01P-1647

Notice of Filing a Pesticide Petition to Establish a Tolerance for a
Certain Pesticide Chemical in or on Food.

See Comments on Page 6

M: (Name, org. symbol, Agency/Post) Linda Hollis OPP/BPPD (7511C)	Room No.-Bldg. 910, CM-2
	Phone No. (703) 308-8733

ROUTING & TRANSMITTAL SLIP

October 10, 2001

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Linda Hollis (concur)	LH	10/11/01 comments pgs. 6
2. Janet Andersen (signature)	JLA	10/17/01
3. Pam Landis (DCN)	PL	10/22
4. Diana Hudson (process)		
5.		

Action	File	Note And Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	X Signature
Coordination	Justify	

REMARKS

FRL No. 6805-7
OPPTS No. 01P-1647

Notice of Filing a Pesticide Petition to Establish a Tolerance for a
Certain Pesticide Chemical in or on Food

Petition No.: 8F-4996, Biosafe Systems

Please put a note in
the weekly that Biosafe
has petitioned for tolerance
exemption amendment and
FP will be published shortly
Thanks! Jim

BPPD#148

FROM: (Name, org. symbol, Agency/Post)	Room No.-Bldg.
Sheleta Diana Hudson	CM-2, 910W33
OPP/BPPD (7511C)	Phone No.
	703-308-8713

a first for you! Nice work.

Note: package given to
Christina 10/22/01 to hand
deliver to Gillis tomorrow.

ENVIRONMENTAL PROTECTION AGENCY

PF-1046; FRL-6805-7]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF-1046 must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Biopesticides and Pollution Prevention Division, (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8733; e-mail address: hollis.linda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

CONCURRENCES							
SYMBOL	7104	7104	7511C	7511C			
SURNAME	Hollis	D. Thomas	D. Hudson	Hollis			
DATE	10/14/01	10/4/01	10/9/01	10-11-01			

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" "Regulation and Proposed Rules," and then look up the entry for this document under the "**Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-1046. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1046 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services

Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

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D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: 10-17-01

James L. Anderson

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BioSafe Systems

PP 8F4996

EPA has received a pesticide petition 8F4996 from Biosafe Systems, 80 Commerce Street, Glastonbury, CT 06033, proposing pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/expansion of an existing tolerance exemption for the biochemical pesticide hydrogen peroxide in or on all postharvest agricultural food commodities at the rate of 1% hydrogen peroxide per application. ✓ ≤ 1/.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Biosafe Systems has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Biosafe Systems and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. duplicate paragraph

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, BioSafe Systems has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by BioSafe Systems and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Hydrogen peroxide is for use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites. BioSafe Systems maintains 2 registrations for 27.00% hydrogen peroxide end-use products, ZeroTol (EPA Reg. No. 70299-1) and Oxidate (EPA Reg. No. 70299-2), for these uses.

B. Product Identity/Chemistry

1. Identity of the pesticide and corresponding residues. Hydrogen peroxide reacts on contact with a surface on which it is applied, and

rapidly degrades to oxygen and water, neither of which is of toxicological concern.

2. *Analytical method.* An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.

C. Mammalian Toxicological Profile

Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ milligrams/kilograms (mg/kg) in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 milligrams per liter (mg/L) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/L (2,000 ppm). Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. A reference dose (RfD) (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

ii. *Drinking water*. At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.

2. *Non-dietary exposure*. There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.

E. Cumulative Exposure

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

F. Safety Determination to the General U.S. Population, and Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at $\leq 1\%$, will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low

concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

G. Effects on the Immune and Endocrine Systems

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

H. Existing Tolerances

An exemption from the requirement of a tolerance (40 CFR 180.1197) is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide, and bactericide.

I. International Tolerances

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

[FR Doc. 01-????? Filed ??-??ndash;01; 8:45 am]

BILLING CODE 6560-50-S



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Memorandum

SUBJECT: Cost of Publishing Documents in the **Federal Register**

FROM: John A. Richards, Director, OPPTS Federal Register Staff (7104)

TO: OPPTS Document Drafters

In view of the limited amount of money that will be available for publishing documents in the **Federal Register** in the current fiscal year, the OPPTS Federal Register Staff is cooperating with budget and program personnel by keeping you informed of printing costs.

This document when prepared with electronic encoding will bill as follows:

Document OPPTS No.: 01P-1647

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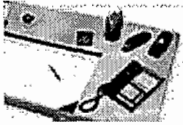
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REQ NO: 0232JHT112

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COST ORG:	SITE/PROJ:	CLOSED AMT:	0.00	
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02- LINE NO:	BFY:	APPR:	RPIO:	
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03- LINE NO:	BFY:	APPR:	RPIO:	
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BOC:	RPTG CATG:	OBLG AMT:		
LAST CHG STATUS:	DESCRIPTION:			

02-*L009 HEADER CHANGE



Diana Hudson

09/19/2001 01:25 PM

To: OPPTS FRStaff@EPA
cc: Linda Hollis/DC/USEPA/US@EPA, (bcc: Diana
Hudson/DC/USEPA/US)
Subject: Biosafe petition 8F4996

Please disregard the earlier version sent to you by Linda Hollis; thank you.

Diana Hudson



biosafe petition 8F4996.w

FILE NAME: biopetit.wpt (4/1/2001)

ATTENTION: All commodity terms must comply with the Food and Feed Commodity Vocabulary database (<http://www.epa.gov/pesticides/foodfeed/>).

**EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY
NOTICE OF FILING TEMPLATE FOR PESTICIDE PETITIONS PUBLISHED IN THE
FEDERAL REGISTER
(4/1/2001)**

EPA Biopesticides and Pollution Prevention Division contact: [Linda Hollis, 703-308-8733]

INSTRUCTIONS: Use this template in preparing your notice of filing for your company's pesticide petition. In cases where the outline element does not apply, insert "NA-Remove" and maintain the outline. The comment balloons appearing in the left margin contain Government Printing Office (GPO) typesetting codes which expedite the **Federal Register** (FR) publication process at EPA for the FR document containing your company's pesticide petition. In the template, do not remove or alter the comment balloons; change the margins, font, or format; or use the WordPerfect comment function. Follow the instructions that appear italicized, color coded, and bracketed.

SUBMISSION: E-mail the completed template to: **hollis.linda@epa.gov**.

TEMPLATE:

EPA has received a pesticide petition [8F4996] from [Biosafe Systems] , [80 Commerce Street, Glastonbury, CT 06033], proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.

Options (pick one)

1. to establish an amendment/expansion of an existing tolerance exemption for the

Options (pick one)

1. biochemical pesticide [hydrogen peroxide]

in or on [all postharvest agricultural food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application].

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, [Biosafe Systems] has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [Biosafe Systems] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. [Biosafe Systems] Petition Summary

[8F4996]

A. Product name and Proposed Use Practices

[FILE NAME: Hydrogen peroxide petition.wpd (9/05/00)]

EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY NOTICE OF FILING TEMPLATE FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

EPA Biopesticides and Pollution Prevention Division contact: [Anne Ball (703) 308-8717]

INSTRUCTIONS: Use this template in preparing your notice of filing for your company's pesticide petition. In cases where the outline element does not apply, insert "NA-Remove" and maintain the outline. The comment balloons appearing in the left margin contain Government Printing Office (GPO) typesetting codes which expedite the **Federal Register** (FR) publication process at EPA for the FR document containing your company's pesticide petition. In the template, do not remove or alter the comment balloons; change the margins, font, or format; or use the WordPerfect comment function. Follow the instructions that appear italicized, color coded, and bracketed.

SUBMISSION: E-mail the completed template to: [ball.anne@epa.gov].

TEMPLATE:

EPA has received a pesticide petition [insert petition number] from [BioSafe Systems, 80 Commerce Street, Glastonbury, CT 06033], proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to

establish an exemption from the requirement of a tolerance for the biochemical pesticide [*Hydrogen peroxide*].

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, [*BioSafe Systems*] has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by [*BioSafe Systems*] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. [*BioSafe Systems*] Petition Summary

[*Insert petition number*]

A. *Product name and Proposed Use Practices*

[Hydrogen peroxide is for use to control plant pathogenic diseases on plants, food commodities, greenhouse surfaces and other agricultural use sites. BioSafe Systems maintains two registrations for 27.00% hydrogen peroxide end-use products, ZeroTol® (EPA Reg. No. 70299-1) and Oxidate® (EPA Reg. No. 70299-2), for these uses.]

B. *Product Identity/Chemistry*

1. *Identity of the pesticide and corresponding residues.*

[Hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which is of toxicological concern.]

2. *Magnitude of residue at the time of harvest and method used to determine the residue.*

[*NA-Remove*]

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.*

[An analytical method for the detection of residues of hydrogen peroxide is not applicable. Hydrogen peroxide is used in low concentrations and rapidly degrades into water and oxygen.]

C. *Mammalian Toxicological Profile*

[Hydrogen peroxide at a concentration of 27% has a pH of 1.05, at which concentration the Agency assumes a toxicity category I for skin and eye irritation. BioSafe Systems has submitted toxicology

information from open literature for aqueous solutions containing 6% and 50% hydrogen peroxide. The concentrate (27% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%.

The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions that contained 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2000 ppm). Solutions that contain 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide, no apparent acute toxicity and subchronic toxicity end-points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized as Safe (GRAS).

Additionally, hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheese-making, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR Part 184.1366). As a GRAS substance, hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).]

D. Aggregate Exposure

1. Dietary exposure.

i. Food.

[For the proposed uses, the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09% - 0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed, and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities (growing and postharvest crops) are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR Part 184.1366).]

ii. *Drinking water.*

[At the proposed application rates, the use of hydrogen peroxide to treat food commodities will result in minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water, neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.]

2. *Non-dietary exposure.*

[There will be minimal amounts of non-dietary exposure to hydrogen peroxide, primarily through infrequent or short use of topical hydrogen peroxide products for treating minor skin injuries, and through use of oral mouthwashes. Exposure is expected to be minimal, and when used hydrogen peroxide rapidly degrades into oxygen and water, neither of which is of toxicological concern.]

E. Cumulative Exposure

[Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.]

F. Safety Determination to the General US Population, and Infants and Children

[Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide, when applied at $\leq 1\%$, will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concluded that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.]

G. Effects on the Immune and Endocrine Systems

[There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.]

H. Existing Tolerances

[40 CFR Part 180.1197 - An exemption from the requirement of a tolerance is established for residues of **hydrogen peroxide** in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algacide, fungicide and

bactericide.]

I. International Tolerances

[There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.]

]

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* [Insert text.]

2. *Magnitude of residue at the time of harvest and method used to determine the residue.*
[Insert text.]

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* [Insert text.]

C. Mammalian Toxicological Profile

[Insert text.]

D. Aggregate Exposure

1. *Dietary exposure.*

i. *Food.* [Insert text.]

ii. *Drinking water.* [Insert text.]

2. *Non-dietary exposure.* [Insert text.]

E. Cumulative Exposure

[Insert text.]

F. Safety Determination

1. *U.S. population.* [Insert text.]

2. *Infants and children.* [Insert text.]

G. Effects on the Immune and Endocrine Systems

[Insert text.]

H. Existing Tolerances

[Insert text.]

I. International Tolerances

[Insert text.]



Group Envsubset/DC/USEPA/US@EPA on 06/21/99 11:11:20 AM

Please respond to epa-pest2@valley.rtpnc.epa.gov

To: epa-pest2@valley.rtpnc.epa.gov

cc:

Subject: Hydrogen Peroxide; Exemption from the Requirement

[Federal Register: June 21, 1999 (Volume 64, Number 118)]

[Rules and Regulations]

[Page 33022-33025]

>From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr21jn99-13]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300872; FRL-6083-9]

RIN 2070-AB78

Hydrogen Peroxide; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide on all food commodities when applied/used as an algicide, fungicide, and bactericide at the rate of 1% hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes. Biosafe Systems submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

DATES: This regulation is effective June 21, 1999. Objections and requests for hearings must be received by EPA on or before August 20, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300872], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW.,

Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300872], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300872]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Anne Ball, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-8717; e-mail address: ball.anne@epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 23, 1998 (63 FR 50901) (FRL-6028-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Biosafe Systems, at that date at 45 E. Woodthrush Trail, East Medford, NJ 08055, at present at 80 Commerce St., Glastonbury, CT 06033. The notice included a summary of the petition prepared by the petitioner Biosafe Systems, the registrant. There were no comments received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide. By this final rule, EPA is granting the petition. EPA is amending the existing exemption for hydrogen peroxide in accordance with the petition. Based on this action, EPA considers the existing exemption to be reassessed.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral LD₅₀ of 5,000 milligram/kilogram (mg/kg) in rats (toxicity category III), an acute dermal LD₅₀ of 10,000 mg/kg in rabbits (toxicity category IV), and an inhalation LC₅₀ of 4 milligram/liter (mg/l) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral LD₅₀ of 500 mg/kg in rats (toxicity category II), and an acute dermal LD₅₀ of 1,000 mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour

exposure of rats to saturated vapors of 90% hydrogen peroxide, LC₅₀ = 4 mg/l (2,000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of 1% hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheesemaking, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. Food. For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09-0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities of the algacide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. Drinking water exposure. At the proposed application rates, the use of hydrogen peroxide as an algacide, fungicide, and bactericide to treat food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

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B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen

peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

IV. Cumulative Effects

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

V. Determination of Safety for U.S. Population, Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide when applied at < 1% will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VI. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application at the time of application (< 1%) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels (MRLs) established for residues of hydrogen peroxide.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 20, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tomkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300872] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also

[[Page 33025]]

include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ``ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously

assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ``to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ``to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.



Fri 1:10 PM 12/10

Ann Roberst

Q Exemption for H_2O_2
Look into Fed Reg Not
AD 202 2828 - 8964

Pulling up new CFR Reg -

GPO CFR - automatic
CFR GPO access - 180.1997
CFR

Summer

Look into

Whylag. *

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 1999.

Kathleen D. Knox,
Acting Director, Biopesticides and Pollution Prevention Division,
Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180-[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1197 is revised to read as follows:

Sec. 180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of < 1% hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.

[FR Doc. 99-15718 Filed 6-18-99; 8:45 am]
BILLING CODE 6560-50-F

FILE NAME: Biopest/tolexemp.wpt

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300XXX; FRL-XXXX-X] (12/1/98)

RIN 2070-[XXXX]

[Hydrogen Peroxide]; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the [*biochemical hydrogen peroxide*] on [*all food commodities*] when applied/used [*as an algicide, fungicide, and bactericide at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes.*]. [*Biosafe Systems*] submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of [*hydrogen peroxide.*]

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received by EPA on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300XXX], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300XXX], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted

electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300XXX]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: [*Anne Ball*], c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2 1921 Jefferson Davis Hwy., Arlington, VA, [703-308-8717], [*Ball.Anne*]@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of [September 23, 1998] (63 FR 50901) (FRL-XXXX-X), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) announcing the filing of a pesticide tolerance petition by [*Biosafe Systems, at that date at 45 E. Woodthrush Trail, East Medford, NJ 08055, at present at 80 Commerce Street, Glastonbury, CT 06033*]. This notice included a summary of the petition prepared by the petitioner [*Biosafe Systems, the registrant*]. [There were no comments received in response to the notice of filing.] The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of [*hydrogen peroxide*]. By this final rule, EPA is granting the petition. EPA is amending the existing exemption for hydrogen peroxide in accordance with the petition. Based on this action, EPA considers the existing exemption to be reassessed.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..."

Additionally, section 408 (b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

[Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral $LD_{50} \leq 500$ mg/kg in rats (toxicity category II), and an acute dermal $LD_{50} \leq 1000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, $LC_{50} = 4$ mg/l (2000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, Hydrogen peroxide is listed by Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally hydrogen peroxide is used to treat food at a maximum level of 0.05 % in milk used in cheesemaking, of 0.04 % in

whey, of 0.15% in starch and corn syrup, and of 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184. 1366). As a GRAS substance hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).]

III. Aggregate Exposures

In examining aggregate exposure, FFDCa section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

[Insert text.]

1. *Food.* [For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09-0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities of the algacide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above(21 CFR 184.1366).]

2. *Drinking water exposure.* [At the proposed application rates the use of hydrogen peroxide as an algacide, fungicide, and bactericide to treat food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.]

B. Other Non-Occupational Exposure

[There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide *into oxygen and water.*]

]

IV. Cumulative Effects

[Because of the low use rates of hydrogen peroxide, its low toxicity and rapid

degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.]

V. Determination of Safety for U.S. Population, Infants and Children

[Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Further the EPA Office of Water has stated that it has seen no new data that contradicts the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VI. Other Considerations

A. Endocrine Disruptors

[There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

[An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

[There are no Codex Maximum Residue Levels (MRLs) established for residues of hydrogen peroxide.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to

“object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by [*insert date 60 days after date of publication in the Federal Register*], file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the “ADDRESSES” section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement “when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.” For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor’s contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300XXX] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the [tolerance/exemption] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their

communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: _____

Director, Biopesticides and Pollution Prevention Division

Therefore, 40 CFR chapter I is amended as follows:

PART 180 [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1197 is removed.

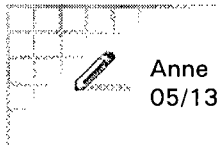
3. Section 180.[1197] is amended to read as follows:

§ 180.[1197] [Hydrogen peroxide; exemption from the requirement of a tolerance.]

[*An exemption* from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.]

[FR Doc. 99-????? Filed ??-??-99; 8:45 am]


BILLING CODE 6560-50-F




Anne Ball
05/13/99 12:06 PM

To: Ttroxell@bangate.fda.gov
cc:
Subject:

I have come across a reference in 21CFR184.1366 : "(b) The ingredient meets the specifications of the Food Chemicals Codex, 3rd ed.(1981), pp.146-147,-----which is incorporated by reference. -----Copies may be obtained from the National Academy of Sciences, -----." The ingredient referred to is hydrogen peroxide. My question is: What is the meaning of the phrase " The ingredient meets the specifications of the Food Chemicals Codex,---"? What are the specifications referred to? I would greatly appreciate a reply. Thank you very much.

 Fred Ives
05/12/99 03:38 PM

To: Anne Ball/DC/USEPA/US@EPA
cc: Randolph Perfetti/DC/USEPA/US@EPA
Subject: Re: "specifications of of the Food Chemicals Codex" 

Anne, sorry, I do not have specific information on this topic. A "Food Chemicals Codex" does not mean necessarily mean it is associated with the international body of Codex (Codex Alimentarius Commission). A "Codex" is merely a compilation of standards, rules or regulations. Thus, a Food Chemicals Codex could be any Codex, international or not. Since you indicate in your voice mail that the citation is a U.S. NAS publication, it sounds like something FDA would be involved with and not necessarily related in all cases to pesticides. You might touch base with someone in FDA concerning the specific reference you cite. Two suggestions:

L. Rober Lake
Director, Office of Policy, Planning and Strategic Initiatives
ph (202) 205-4160
FAX (202) 205-4160
E:mail rlake@bangate.fda.gov OR:

Dr. Terry C. Troxell, FDA
Director, Office of Plant and Dairy Foods and Beverages
ph (202) 205-4681
FAX (202) 205-4422
E-mail ttroxell@bangate.fda.gov


I am also aware that FAO has some kind of pesticide specifications and I believe are considering updating them. You may access information on the internet at:

<http://www.fao.org/WAICENT/FaoInfo/Agricult/AGP/AGPP/Pesticid/default.htm>

I hope this helps.

Fred

Anne Ball

 Anne Ball
05/12/99 02:40 PM

To: Fred Ives/DC/USEPA/US@EPA
cc:
Subject: "specifications of of the Food Chemicals Codex"

Could you please explain the phrase "... ingredient meets the SPECIFICATIONS of the Food Chemicals Codex, 3rd ed. (1981) etc....." This reference was incorporated in the FDA listing of substances Generally Regarded as Safe (GRAS) in 21CFR 184. Specifically it appears in Sec. 184.1366, referring to the chemical hydrogen peroxide. I would be much obliged -your response.

[Code of Federal Regulations]
[Title 21, Volume 3, Parts 170 to 199]
[Revised as of April 1, 1998]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1366]

[Page 484-485]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CO
PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1366 Hydrogen peroxide.

(a) Hydrogen peroxide (H<INF>2</INF>O<INF>2,</INF> CAS Reg. No. 7722-84-1) is also referred to as hydrogen dioxide. It is made by the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt with subsequent hydrolysis and distillation of the hydrogen peroxide formed; by decomposition of barium peroxide with sulfuric or phosphoric acid; by hydrogen reduction of 2-ethylanthraquinone, followed by oxidation with air, to regenerate the quinone and produce hydrogen peroxide; or by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, —

[[Page 485]]

3d ed. (1981), pp. 146-147,¹ which is incorporated by reference.

¹ Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with Sec. 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under part 133 of this chapter.	0.05.....	Antimicrobial agent as defined in Sec. 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods.	0.04.....	do.
Dried eggs, dried egg whites, and dried egg yolks as in Secs. 160.105, 160.145, and 160.185 of this chapter.	Amount sufficient for the purpose.	Oxidizing and reducing agent as defined in Sec. 170.3 (o)(22) of this

Tripe.....	do.....	chapter
Beef feet.....	Amount sufficient for the purpose. (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide).	Bleaching agent. Bleaching agent.
Herring.....	Amount sufficient for the purpose.	do.
Wine.....	do.....	Oxidizing and reducing agent as defined in Sec. 170.3 (o)(22) of this chapter.
Starch.....	0.15.....	Antimicrobial agent as defined in Sec. 170.3 (o)(2) of this chapter, to produce thermophile- free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea.....	Amount sufficient for the purpose.	Bleaching agent.
Corn syrup.....	0.15.....	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey.	0.05.....	Bleaching agent.
Wine vinegar.....	Amount sufficient for the purpose.	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.
Emulsifiers containing fatty acid esters.	1.25.....	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[46 FR 44439, Sept. 4, 1981, as amended at 51 FR 27172, July 30, 1986]



Dan Schmelling@EPA on 04/09/99 05:17:30 PM

202 260 1439

To: Ball.Anne
cc:
Subject:

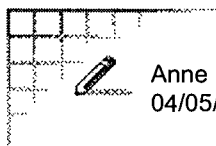
Ann:

This is in response to your question concerning the health risk posed by hydrogen peroxide residues in drinking water, resulting from the use of hydrogen peroxide as an algaecide, fungicide, and bactericide. This office has seen no new data that contradicts the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk.

Regards,
Dan Schmelling

>>> <Ball.Anne@epamail.epa.gov> 04/05/99 07:48pm >>>

The Biopesticides and Pollution Prevention Division of OPP of EPA is about to publish a Final Rule for the exemption from the requirement of a tolerance for hydrogen peroxide when used as an algaecide, fungicide, and bactericide at the rate of less than or equal to 1% hydrogen peroxide per application on growing crops(all food commodities) and postharvest potatoes. This regulation serves to reassess existing tolerances for the active ingredient hydrogen peroxide, specifically as seen in 40 CFR Section 180.1197 published May 6, 1998 by the Antimicrobials Division of OPP of EPA. My request concerns the view of the EPA Office of Water at this time regarding the existence of residues of hydrogen peroxide in drinking water as a result of its use as an algaecide, fungicide, and bactericide. This opinion is needed at this time in the section on chronic exposure and risk from drinking water (a topic required by FQPA). I would very much appreciate a reply as soon as you are able. Have you seen any data to change your assessment of May 1998 as shown in the document cited above? I thank you very much.



Anne Ball
04/05/99 07:48 PM

To: Schmelling.dan@epamail.epa.gov
cc:
Subject:

The Biopesticides and Pollution Prevention Division of OPP of EPA is about to publish a Final Rule for the exemption from the requirement of a tolerance for hydrogen peroxide when used as an algaecide, fungicide, and bactericide at the rate of less than or equal to 1% hydrogen peroxide per application on growing crops(all food commodities) and postharvest potatoes. This regulation serves to reassess existing tolerances for the active ingredient hydrogen peroxide, specifically as seen in 40 CFR Section 180.1197 published May 6, 1998 by the Antimicrobials Division of OPP of EPA. My request concerns the view of the EPA Office of Water at this time regarding the existence of residues of hydrogen peroxide in drinking water as a result of its use as an algaecide, fungicide, and bactericide. This opinion is needed at this time in the section on chronic exposure and risk from drinking water (a topic required by FQPA). I would very much appreciate a reply as soon as you are able. Have you seen any data to change your assessment of May 1998 as shown in the document cited above? I thank you very much.

envsubset
03/30/99 10:42 AM

Please respond to epa-meetings2@valley.rtpnc.epa.gov

To: epa-meetings2@valley.rtpnc.epa.gov

cc:

Subject: Notice of Public Meeting on Drinking Water Issues

[Federal Register: March 30, 1999 (Volume 64, Number 60)]

[Notices]

[Page 15157]

>From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr30mr99-30]

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6316-8]

Notice of Public Meeting on Drinking Water Issues

Notice is hereby given that the U.S. Environmental Protection Agency (EPA) is holding a meeting on April 28-29, 1999, at Resolve, 1255 23rd St., NW, Suite 275, Washington, DC 20037, for the purpose of exchanging technical information on issues related to the use of ultraviolet (UV) radiation for disinfection of drinking water. The meeting will start at 8:30 a.m. on Wednesday, April 28 and will adjourn on Thursday, April 29 at 4:00 p.m. The meeting will provide an evaluation of the current status of knowledge and prioritize additional research needs related to selected aspects of UV disinfection of drinking water. The public is invited to attend the meeting as observers. Seating is very limited so advance registration is required.

For additional information about the meeting and to register, please contact Dan Schmelling of EPA's Office of Ground Water and Drinking Water at (202) 260-1439 or by e-mail at schmelling.dan@epamail.epa.gov.

Dated: March 23, 1999.
Cynthia C. Dougherty,
Director, Office of Ground Water and Drinking Water.
[FR Doc. 99-7776 Filed 3-29-99; 8:45 am]
BILLING CODE 6560-50-P

ROUTING & TRANSMITTAL SLIP

April 13, 1999

TO: (Name, office symbol, room number, building,
Agency/Post)
Meshteh Toghrol, BPPD, CM2910

Initials

Date

F.T.

4/13/99

No comment

2. Jon Fleuchaus, OGC, WSM W539, Mail Code 2333

3.

4.

5.

	Action		File		Note And Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
x	Comment		Investigate		Signature
	Coordination		Justify	x	Initials, Concurrence

REMARKS

I have incorporated in the attached copy the combined changes which you both have made in the copy, dated March 5, 1999, of the draft Final Rule which establishes an exemption from the requirement of a tolerance for residues of the chemical hydrogen peroxide in or on all food commodities when applied as fungicide, fungicide and bactericide at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes. I have revised, and added the comment of the EPA Office of Water to, Part III A 2 "Drinking Water Exposure". I have revised as well Part IV "Cumulative Effects".

Please note that the material which appears in medium black print is "boilerplate" material. Please direct your attention to the inserted text which appears in either bold italic, bold, or shadowy grey print.

I would greatly appreciate it if you could return any comment and your concurrence to me by COB April 19. I am hoping to have this Final Rule published before the end of this month. Thank you very much.

FROM: (Name, org. symbol, Agency/Post)
Ball, BPPD, Mail Code 7511C

Room No.-Bldg.
RM 910-CM2

Phone No.
308-8717

ASB 4/13/99

FILE NAME: Biopest\tolexemp.wpt

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300XXX; FRL-XXXX-X] (12/1/98)

RIN 2070-[XXXX]

[Hydrogen Peroxide]; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the **[biochemical hydrogen peroxide]** on **[all food commodities]** when applied/used **[as an algacide, fungicide, and bactericide at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes.]**. **[Biosafe Systems]** submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of **[hydrogen peroxide.]** EPA also proposes to remove any existing crop-specific tolerances and/or exemptions from the requirement of a tolerance for hydrogen peroxide as well as considering such tolerances to be reassessed as required by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective *[insert date of publication in the Federal Register]*. Objections and requests for hearings must be received by EPA on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300XXX], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300XXX], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921

Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300XXX]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: [*Anne Ball*], c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2 1921 Jefferson Davis Hwy., Arlington, VA, [703-308-8717], [*Ball.Anne*]@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of [*September 23, 1998*] (63 *FR* 50901) (FRL-XXXX-X), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) announcing the filing of a pesticide tolerance petition by [*Biosafe Systems, at that date at 45 E. Woodthrush Trail, East Medford, NJ 08055, at present at 80 Commerce Street, Glastonbury, CT 06033*]. This notice included a summary of the petition prepared by the petitioner [*Biosafe Systems, the registrant.*]. [There were no comments received in response to the notice of filing.] The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of [*hydrogen peroxide*].

EPA concurrently proposes the removal of the existing crop-specific exemption from the requirement of a tolerance for hydrogen peroxide when used as an algacide, fungicide, and bactericide. In taking this action EPA will consider that exemption to be reassessed. (Federal Food, Drug and Cosmetic Act, 408(q) as amended by the FQPA of 1996).

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in

residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..." Additionally, section 408 (b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

[Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral LD₅₀ ~~≥ 5000~~ mg/kg in rats (toxicity category III), an acute dermal LD₅₀ ~~≥ 10000~~ mg/kg in rabbits (toxicity category IV), and an inhalation LC₅₀ of 4 mg/l (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral LD₅₀ ~~≤ 500~~ mg/kg in rats (toxicity category II), and an acute dermal LD₅₀ ~~≤ 1000~~ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC₅₀ = 4 mg/l (2000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of

residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..." Additionally, section 408 (b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

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[Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral $LD_{50} \leq 500$ mg/kg in rats (toxicity category II), and an acute dermal $LD_{50} \leq 1000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, $LC_{50} = 4$ mg/l (2000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of

infants and children. Additionally, Hydrogen peroxide is listed by Food and Drug Administration as Generally Recognized As Safe (GRAS) and meets the specifications of the Food Chemicals Codex. Additionally hydrogen peroxide is used to treat food at a maximum level of 0.05 % in milk used in cheesemaking, of 0.04 % in whey, of 0.15% in starch and corn syrup, and of 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184. 1366). As a GRAS substance hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).]

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

[Insert text.]

1. *Food.* [For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09-0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities of the algacide/fungicide/bactericide hydrogen peroxide are expected to be negligible. In considering the very low mammalian toxicity related to the concentrations of the proposed hydrogen peroxide product as shown above and even when considering the additional source of the GRAS substance hydrogen peroxide in concentrations ranging from 0.04% to 1.25% in various foods as cited above(21 CFR 184.1366), the use at application rates of $\leq 0.54\%$ is expected to have no harmful effect on humans through dietary exposure.]

2. *Drinking water exposure.* [At the proposed application rates the use of hydrogen peroxide as an algacide, fungicide, and bactericide to treat food commodities could result in additional minimal transfer of residues to potential drinking water sources. However no risk assessment is required because of the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern. The EPA Office of Water has stated that it has seen no new data that contradicts the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk]

B. Other Non-Occupational Exposure

[The increased use pattern proposed for hydrogen peroxide will increase exposure to hydrogen peroxide. However, because of the very low level of mammalian toxicity and the

rapid degradation of hydrogen peroxide into oxygen and water, such exposure will not be harmful to humans.]

1. *Dermal exposure.* [Because of the rapid degradation of hydrogen peroxide such exposure will not be harmful to humans.*Insert text.*]

2. *Inhalation exposure.* [Because of the rapid degradation of hydrogen peroxide such exposure will not be harmful to humans.*Insert text.*]

IV. Cumulative Effects

[Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide. EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.*Insert text.*]

V. Determination of Safety for U.S. Population, Infants and Children

[Because hydrogen peroxide is of low toxicity, *the proposed* uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Accordingly EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VI. Other Considerations

A. Endocrine Disruptors

[*There is no* evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

[*An analytical* method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

[***There are no Codex Maximum*** Residue Levels (MRLs) established for residues of hydrogen peroxide.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by [*insert date 60 days after date of publication in the Federal Register*], file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the “ADDRESSES” section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement “when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.” For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor’s contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action

requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300XXX] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates

Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the [tolerance/exemption] in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal

government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ``to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: _____

Director, Biopesticides and Pollution Prevention Division

Therefore, 40 CFR chapter I is amended as follows:

PART 180_[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1197 is removed.

3. Section 180.[1197] is amended to read as follows:

§ 180.[1197] ***[Hydrogen peroxide; exemption from the requirement of a tolerance.]***

[An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.]

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 6560-50-F

ROUTING & TRANSMITTAL SLIP

March 5, 1999

TO: (Name, office symbol, room number, building, Agency/Post)		Initials	Date
Shsteh Toghrol, BPPD, CM2 910		F.T.	3/8/99
2. Roy Sjoblad, BPPD, CM2 910		na	3/10/99
3. Jon Fleuchaus, OGC, WSM W539, MailCode2333			
4. Phil Hutton, BPPD, CM2 910			
5. Marshall Swindell, AD, CM2 308H, 7510C			
Action	File	Note And Return	
Approval	For Clearance	Per Conversation	
As Requested	For Correction	Prepare Reply	
Circulate	For Your Information	See Me	
X Comment	Investigate	Signature	
Coordination	Justify	x	Initials, Concurrence

REMARKS

Please initial with your comment/concurrence concerning the attached copy of a draft Final Rule which establishes an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide in or on all commodities when applied as an algacide, fungicide and bactericide at the of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes.

This regulation serves to reassess an exemption from the requirement of a tolerance established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices. (See Federal Register May 6, 1998, Volume 63, No. 87). (40 CFR 180.1197).

Please note that the material which appears in medium black print is "fillerplate" material. Please direct your attention to the inserted text which appears in either bold italic, bold, or shadowy grey print.

Please return your concurrence/comments to me by COB March 12.

AMNE -
was pulled &
FED on
H₂O₂?

Renegotiation 1993

FROM: (Name, org. symbol, Agency/Post)	Room No.-Bldg. Rm 910-CM2
Anne Ball, BPPD, Mail code 7511C	Phone No. 308-8717

ROUTING & TRANSMITTAL SLIP

March 5, 1999

(Name, office symbol, room number, building, Agency/Post)		Initials	Date
1. Preshteh Toghol, BPPD, CM2 910			
2. Roy Sjoblad, BPPD, CM2 910			
3. Jon Fleuchaus, OGC, WSM W539, MailCode2333		<i>JD</i>	12/27/98 4/7/99
4. Phil Hutton, BPPD, CM2 910			
5. Marshall Swindell, AD, CM2 308H, 7510C			
	Action	File	Note And Return
	Approval	For Clearance	Per Conversation
	As Requested	For Correction	Prepare Reply
	Circulate	For Your Information	See Me
x	Comment	Investigate	Signature
	Coordination	Justify	x Initials, Concurrence

REMARKS

Please initial with your comment/concurrence concerning the attached copy of a draft Final Rule which establishes an exemption from the requirement tolerance for residues of the biochemical hydrogen peroxide in or on all commodities when applied as an algacide, fungicide and bactericide at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes.

This regulation serves to reassess an exemption from the requirement of a tolerance established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices. (See Federal Register May 6, 1998, Volume 63, No. 87). (40 CFR 180.1197).

Please note that the material which appears in medium black print is "fillerplate" material. Please direct your attention to the inserted text which appears in either bold italic, bold, or shadowy grey print.

Please return your concurrence/comments to me by COB March 12.

FROM: (Name, org. symbol, Agency/Post)	Room No.-Bldg. Rm 910-CM2
Anne Ball, BPPD, Mail code 7511C	Phone No. 308-8717

MAR 9 1999



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Roy Sjoblad
Chief, Biochemicals Branch
Biopesticides and Pollution Prevention Division (7511W)
Office of Pesticide Programs
1921 Jefferson Davis Highway
Arlington, VA 22202

June 24, 1998

RE: Petition for an exemption from the requirement of a tolerance for residues of products containing the active ingredient HYDROGEN PEROXIDE, in and on all ~~raw~~ agricultural commodities, when applied as a pesticide to growing agricultural crops.

food

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Mr. Sjoblad:

With this letter Technology Sciences Group, on behalf of BioSafe Systems (EPA Company No. 70299), hereby submits a petition for the following:

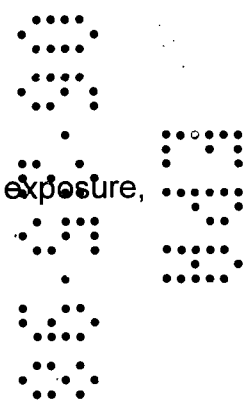
An exemption from the requirement of a tolerance for residues of products containing the active ingredient **hydrogen peroxide**, in and on all raw agricultural commodities, when used as a pesticide on growing agricultural crops, in accordance with 40 CFR Part 180 and pursuant to Section 408(d)(1) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

In support of this petition, attached you will find the following information, submitted in duplicate:

- A. Summary of product chemistry;
- B. Proposed use practice;
- C. Toxicological profile;
- D. Aggregate exposure, including information on dietary exposure, drinking water exposure and non-dietary exposure;
- E. Cumulative effects;





WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Page 2
June 24, 1998

- F. Safety determination, including information on the U.S. general population, and infants and children;
- G. Existing tolerances;
- H. Information on endocrine effects.

Information listed above has already been reviewed by EPA and most of the summaries provided reflect the findings of Agency reviewers. The petitioner agrees that the enclosed information may be published as part of the notice of filing of the petition, to be published under Section 408(d)(1), and as proposed for final regulation.

SAN FRANCISCO

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

Please note on April 30, 1998 an exemption from the requirement of a tolerance was established for hydrogen peroxide, up to 120 ppm, in or on raw agricultural commodities and in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices (40 CFR Part 180.1197). The established exemption specifies the use of hydrogen peroxide as an antimicrobial agent. BioSafe Systems proposes other uses of hydrogen peroxide, specifically as an algicide, fungicide, bactericide and insecticide, and believes that a new exemption is required to include those uses.

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

With this letter we are also requesting a **waiver of the fee for filing a petition** for an exemption from the requirement of a tolerance, for the following reasons:

- 1) Hydrogen peroxide is an already registered active ingredient with an established tolerance exemption for similar uses. The active ingredient reacts on contact and the degradation products (oxygen and water) are not of toxicological concern. Hydrogen peroxide does not pose any potential for unreasonable adverse effects to human health;



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
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Fax 202 872-0745

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June 24, 1998

- 2) The fee for filing a petition for an exemption from the requirement of a tolerance would pose unreasonable hardship on the registrant, BioSafe Systems. BioSafe is a small, family-owned company that currently maintains one EPA registered product (hydrogen peroxide for use as an algicide / fungicide on ornamental plants and turf - EPA Reg. No. 70299-1). At this time the fee would present undue financial strain on the company.

We have submitted the appropriate fee (\$1,550) for filing a waiver request to EPA Headquarters Accounting Operations Branch, Pittsburgh, PA, on this date, with a copy of this letter included for reference.

Should you have any questions or comments on this petition please contact me directly.

Sincerely,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems
(202) 828-8964

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

COPY



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

<sent via Certified Mail, article number P 175 814 700>

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs (Tolerance Fees)
P.O. Box 360277M
Pittsburgh, PA 15251

June 24, 1998

RE: Tolerance Petition Fees

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear HQ Accounting Operations Branch:

With this letter Technology Sciences Group, on behalf of BioSafe Systems (EPA Company No. 70299), hereby submits the following in support of a petition for an exemption from the requirement of a tolerance:

- 1) Check for \$1,550 - fee for requesting a waiver of the fees for filing a petition for an exemption from the requirement of a tolerance.
- 2) Copy of the cover letter submitted with the petition; includes rationale for waiver of the filing fee.

Should you have any questions or comments, please contact me directly at (202) 828-8964.

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Sincerely,

A handwritten signature in black ink, appearing to read 'Amy Plato Roberts', written over a horizontal line.

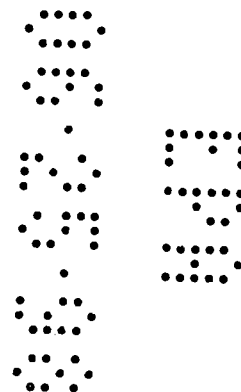
Amy Plato Roberts
Regulatory Consultant for BioSafe Systems

**Petition for an exemption from the requirement of a tolerance
for residues of products containing the active ingredient
HYDROGEN PEROXIDE, in and on all raw agricultural
commodities, when used as an algicide, bactericide,
fungicide and/or insecticide**

June 24, 1998

Submitted by: Technology Sciences Group, Inc.
1101 17th Street, N.W., Suite 500
Washington, D.C. 20036

Submitted for: BioSafe Systems (EPA Company No. 70299)
45 E. Woodthrush Trail
East Medford, NJ 08055



SECTION A - SUMMARY OF PRODUCT CHEMISTRY

Product Name: ZeroTol™ Broad Spectrum Algicide/Fungicide
[27% Hydrogen Peroxide (Hydrogen Dioxide)]
[EPA Reg. No. 72099-1]

Oxidate™ Broad Spectrum Algicide/Fungicide
[27% Hydrogen Peroxide (Hydrogen Dioxide)]
[Not yet applied for]

Active Ingredient: Hydrogen Peroxide (Hydrogen Dioxide)
CAS Number: 772-84-1
Molecular Formula: H₂O₂
Molecular Weight: 34.02

Color: Colorless —
Physical State: Liquid —
Odor: Moderately pungent —
Boiling Point: 100°C —
Specific Gravity: 1.091 at 22°C —
Solubility: Soluble in water —
pH: 1.05 at 25°C —
Flammability: Non-flammable —
Explodability: Non-explosive —
Storage Stability: Unstable at 50°C for 30 days —
Viscosity: 0.78 cS at 22°C —
Corrosion Characteristics: Moderately corrosive —

Mode of Action:

The mode of action of hydrogen peroxide is oxidation. Hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which are of toxicological concern.

Analytical Method:

Refer to MRID No. 441160-02, Preliminary Analysis and Precision and Accuracy of Analytical method Used to Calibrate Certified Limits.

History of Use:

Hydrogen peroxide is currently registered for pesticidal use as an antimicrobial for the control of bacteria, fungi and viruses. Originally registered in 1977, hydrogen

peroxide products are used as disinfectants, sanitizers and sterilants in commercial, industrial and medical settings; including but not limited to, agricultural premises, dairy/food handling and food processing facilities, commercial facilities, eating establishments, reverse osmosis water systems, and critical and noncritical hospital settings. In its 1993 Reregistration Eligibility Decision on Peroxy Compounds, EPA concluded the use of hydrogen peroxide and other peroxy compounds does not pose an unreasonable risk or adverse effect to humans or the environment. Hydrogen peroxide is generally regarded as safe (GRAS) according to the Food and Drug Administration (FDA) (21 CFR Part 178) when used as a food additive and when used on food-processing equipment, utensils, and food contact articles. Hydrogen peroxide is also approved for medicinal use in hospitals and homes.

Hydrogen Peroxide for Agricultural Uses:

BioSafe System's product ZeroTol™ was registered in February 1998 as a biochemical for the control of plant pathogenic diseases on ornamentals and turf, and on greenhouse surfaces. Due to the fact that hydrogen peroxide is known to occur naturally, and that there is a wide body of published literature and previously submitted safety data, for agricultural uses as on the ZeroTol™ label hydrogen peroxide was considered a reduced risk pesticide and qualified for reduced data requirements as a biochemical with the Biopesticides and Pollution Prevention Division, EPA.

Ecolab Inc. has recently registered hydrogen peroxide (at 11% and 14.9% active ingredient concentration by weight) for food uses as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices, and has been issued an exemption from the requirement of a tolerance for residues up to 120 ppm, when used as an antimicrobial agent on those agricultural crops (40 CFR Part 180.1197).

For further information, refer to the following submitted studies:

MRID No. 441160-01	Product Chemistry of Zero Tolerance Algaecide, Fungicide, Disinfectant
MRID No. 441160-02	Preliminary Analysis and Precision and Accuracy of Analytical method Used to Calibrate Certified Limits
MRID No. 443402-01	Measurement of Physico-Chemical Properties

SECTION B - PROPOSED USE PRACTICE

BioSafe Systems has already registered hydrogen peroxide (27% active ingredient concentration by weight) for use as an algicide, bactericide and fungicide to control plant pathogenic diseases on ornamentals and turf (ZeroTol™ Broad Spectrum Algicide / Fungicide, EPA Reg. No. 70299-1). BioSafe intends to pursue the same use pattern (bactericide, fungicide) as a plant dip, soil drench and foliar spray on the following food crops in greenhouse and agricultural use sites (such as nurseries):

- Beans
- Broccoli
- Cauliflower
- Cabbage
- Cucurbits
- Onions
- Peppers
- Potatoes (including seed potatoes)
- Tomatoes
- Apples
- Filberts
- Bananas
- Grapes
- Peaches
- Plums
- Cherries
- Nectarines
- Prunes

In addition, at a later date BioSafe intends to pursue an application for registration of hydrogen peroxide for use as an insecticide to control greenhouse pests, such as fungus gnats, whiteflies, thrips, aphids, mealy bugs and scale, on ornamental and food crops.

A proposed food use label is found immediately following this page.



Oxidate™



Broad Spectrum Bactericide / Fungicide

DRAFT

- * Preventative treatment for growing plants, fruits, nuts and vegetables.
- * A treatment for the prevention and control of plant pathogenic diseases in the field, commercial greenhouses, garden centers, landscapes, nurseries and interiorscapes.

FOR AGRICULTURAL AND COMMERCIAL USE ONLY

ACTIVE INGREDIENT:

Hydrogen Peroxide..... 27%

INERT INGREDIENTS:..... 73%

TOTAL:..... 100%

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

*Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand this label, find someone to explain it to you in detail.)*

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get immediate medical attention.

IF ON SKIN: Remove contaminated clothing and wash affected areas with plenty of soap and water. Get immediate medical attention.

IF SWALLOWED: Call a physician or poison control center immediately. Drink large quantities of water. Do not induce vomiting. Avoid alcohol. Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED: Remove victim to fresh air. Get immediate medical attention.

See side panel for additional precautionary statements.

Sold by: BioSafe Systems, 45 E. Woodthrush Trail, Medford, NJ 08055

EPA Registration No. 70299-

EPA Establishment No. 68660-TX-01

Net Contents: 2.5 gallons

Oxidate Broad Spectrum Bactericide/Fungicide
Last revised June 24, 1998

Page 5 of 19
Hydrogen Peroxide Tolerance Exemption

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CORROSIVE: Concentrate causes irreversible eye damage. Concentrate may be fatal if swallowed. Concentrate causes skin irritation or temporary discoloration on exposed skin. Do not breathe vapor of concentrate. Do not get concentrate in eyes, on skin or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

When handling concentrate wear protective eyewear (goggles or face shield) and rubber gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water.

USER SAFETY RECOMMENDATIONS

Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

FOR TERRESTRIAL USES. Keep out of lakes, ponds and streams. This pesticide is toxic to birds and fish. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wash waters.

This product is highly toxic to bees and other beneficial insects exposed to direct contact on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. Do not apply this product or allow it to drift to crops where beneficials are part of an Integrated Pest Management strategy.

PHYSICAL AND CHEMICAL HAZARDS

Strong oxidizing agent. **Corrosive.** Do not use in concentrated form. Mix only with water in accordance with label instructions. Never bring concentrate in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about Personal Protective Equipment (PPE) and Restricted-Entry Interval (REI). The requirements in this box only apply to the uses of this product that are covered by the Worker Protection Standard.

There is a restricted entry of zero (0) hours for this product.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: long-sleeved shirt, long pants, and shoes plus socks.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinses (or equivalent). Then offer for recycling or dispose in a sanitary landfill, or incineration, if allowed by state and local authorities by burning, stay out of smoke.

DIRECTIONS FOR USE:

- * Oxidate™ works best when diluted with water containing low levels of organic or inorganic materials, and with water having a neutral pH. Thoroughly rinse out tank with water before mixing concentrate. Oxidate™ will readily mix with clean, neutral water and does not require agitation.
- * Oxidate™ should not be combined or mixed with any other pesticide or fertilizer.
- * Oxidate™ is formulated with a minimal amount of surfactant for plants having waxy or hairy surfaces. Additional surfactant may be added at a rate of 1 to 2 ounces per gallon, if needed.

Oxidate™ works by surface contact with the plants and materials being treated. It is important to ensure that all surfaces are thoroughly wetted. Oxidate™ does not produce any visible residue, distinct odor or deleterious effects to plants when used in accordance with label directions. Do not use at higher than recommended dilution rates as leaf burn may result.

Oxidate Broad Spectrum Bactericide/Fungicide

Last revised June 24, 1998

Do not apply this product through any irrigation system unless directed by the label; refer to Chemigation Directions for Use.

Use Rates and Directions:

Pre-Plant Dip Treatment -

Use Oxidate™ for the control of damping-off, root disease and stem rot disease caused by *Pythium*, *Phytophthora*, *Rhizoctonia*, *Fusarium* or *Thielaviopsis*, on seeds, seedlings, bulbs, or cuttings.

- 1) Mix 64 fl. oz. per 50 gallons of water.
- 2) Immerse plants or cuttings; remove and allow to drain. Do not rinse.

Soil Drench -

Oxidate™ is effective for the control of soil borne plant diseases such as *Pythium*, *Phytophthora*, *Rhizoctonia*, *Thielaviopsis* or *Fusarium*. Use as a soil drench at the time of seeding or transplanting, as well as a periodic drench throughout the plant's life. Oxidate™ can also be used on potting soil and growing mediums prior to planting.

- 1) Mix 2½ fl. oz. Oxidate™ per gallon of clean water.
- 2) Apply to soil or growing media to the point of saturation.
- 3) Wait fifteen minutes before planting or watering.

Foliar Spray Treatments for field grown crops, crops grown in commercial greenhouses or crops grown in other similar sites -

Oxidate™ works immediately on contact with any plant surface for control. Good coverage and wetting of the foliage is necessary.

Crops	Disease	Dilution Rate Application Rate	Directions
Beans	Anthracnose Downy Mildew Powdery Mildew Rust	1:100 – 1:300 [40–128 oz. of concentrate per 100 gallons of water.]	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1:100 [50 – 100 gallons of spray solution per acre. 128 oz. of concentrate per 100 gallons of water.]	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Broccoli Cauliflower Cabbage	Alternaria Leaf Spot Downy Mildew Powdery Mildew	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1:100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

Oxidate Broad Spectrum Bactericide/Fungicide
Last revised June 24, 1998

Crops	Disease	Dilution Rate	Directions
Cucurbits	Alternaria Anthracnose Downy Mildew Powdery Mildew Pythium Rot	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1: 100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Onions	Botrytis Downy Mildew Powdery Mildew	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1: 100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Peppers	Anthracnose Phytophthora Blight Powdery Mildew	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1: 100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Potatoes	Early Blight Late Blight	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1: 100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Seed Potatoes	Fusarium	1: 50	Dip whole or cut tubers into tank of working solution. Let soak for a period of five minutes before removing seed pieces.
Tomatoes	Anthracnose Cladosporium Mold Early Blight Late Blight Powdery Mildew	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1: 100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Apples	Rusts Scab Powdery Mildew	1:100	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
		1: 100	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

Oxidate Broad Spectrum Bactericide/Fungicide
Last revised June 24, 1998

Crops	Disease	Dilution Rate	Directions
Filberts	Eastern Filbert Blight Bacterial Blight	1:100 1: 100	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Bananas	Sigatoka	1:100 – 1: 300 1:100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Grapes	Black Rot Downy Mildew Powdery Mildew	1:100 – 1: 300 1:100	Preventive: Begin when shoots are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Stone Fruits Peaches Plums Cherries Nectarines Prunes	Downy Mildew Powdery Mildew Brown Rot	1:100	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

Chemigation Directions for Use

General Requirements:

- 1) Apply this product only through a sprinkler including a center pivot, lateral move, end tow, side wheel roll, traveler, solid set, hand move, flood basin or drip trickle irrigation system. Do not apply this product through any other type of irrigation system.
- 2) Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.
- 3) Ensure that the irrigation system used is properly calibrated and if you have questions, call the state extension service or the equipment manufacturer.
- 4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless proper safety devices for public water systems are in place. Read label for instructions.
- 5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

(Chemical Directions for Use, cont.)

Specific Requirements:

- 1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
- 2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top of the overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- 3) The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of liquid back towards the injector.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid, operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being drawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump, or equivalent, effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Application Instructions:

- 1) Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and entire injector system. Flush with clean water. Failure to provide a clean tank, void of scale or residues may cause product to lose effectiveness or strength.
- 2) Determine the treatment rates as indicated in the directions for use and make proper dilutions.
- 3) Prepare a solution in the chemical tank by filling the tank with the required water and then adding product as required. The product will immediately go into suspension without any required agitation.
- 4) Oxidate should not be applied in conjunction with any other pesticides or fertilizers; this may cause reduced performance of the product and should be avoided.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, method of application, weather, watering practices, nature of soil, potting medium, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

use in tote

SECTION C - TOXICOLOGICAL PROFILE

BioSafe Systems proposes products containing 27% hydrogen peroxide, by weight. In all cases the product is diluted with water, at a rate of 1:50, 1:100 or 1:300, which results in a concentration of 0.25% to 1.50% hydrogen peroxide in the product that is applied.

As hydrogen peroxide is a well known, well-tested active ingredient, BioSafe Systems has relied on published literature to fulfill toxicity data requirements. Open literature information submitted indicates that hydrogen peroxide is toxic at high levels, but that a 1.5% concentration it has no impact on human skin, eyes or respiratory systems. As the BioSafe products (the concentrate before dilution with water) have a pH of 1.05, they are rated Toxicity Category I for skin and eye irritation, and carry the appropriate label warnings and personal protective equipment for that category. For the oral route of exposure, a concentration of 0.5% hydrogen peroxide was determined not to present a potential adverse effect; due to the fact that hydrogen peroxide, at concentrations of 0.04 and 0.05%, has been classified as GRAS by FDA (184.1366) and USDA for use as a food additive, toothpaste or mouthwash. Per EPA request, for maximum protection BioSafe product labels for agricultural use have precautionary statements based on toxicity study results reported for a 50% concentration hydrogen peroxide solution, as noted below.

A summary of open literature previously submitted is as follows:

Solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). Such solutions are mild irritants to rabbit skin and cause severe, irreversible corneal injury in half of the exposed rabbits (toxicity category I).

Solutions containing 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2000 ppm). Solutions containing 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I). Weak direct mutagenicity responses were seen for hydrogen peroxide in Ames tests with *Salmonella typhimurium* strains TA97, TA98, TA102 and TA1537 in a 20 minute preincubation test and in a liquid incubation modification using strain TA1537.

In the above studies, the effects were observed on the eye and skin.

Additional information regarding immunotoxicity, development toxicity and chronic toxicity (at various concentrations of hydrogen peroxide) was also submitted from the open literature. For more information refer to **MRID No. 441160-05**, Review of Hydrogen Peroxide Toxicity.

Further information can also be referenced from the established exemption from the requirement of a tolerance of hydrogen peroxide when used as an antimicrobial agent, *not* which states the following:

(Excerpts of Federal Register from May 6, 1998 [Volume 63, Number 87, Pages 24955 - 24963])

"Hydrogen peroxide is highly reactive and short lived because of the inherent instability of the peroxide bond (i.e., the O-O bond). Agitation or contact with rough surfaces, sunlight, organics and metals accelerates decomposition. The instability of hydrogen peroxide to exist as itself, along with detoxifying enzymes found in cells (e.g., catalase, glutathione peroxidase), makes it very difficult to find any residues of hydrogen peroxide in or on foods (at proposed use levels), by conventional analytical methods." *3- ✓*

"Residues are not of toxicological concern because hydrogen peroxide decomposes rapidly into oxygen and water. The Agency has no toxicological concern with oxygen and water." *not*

"Therefore, the lack of residues of toxicological concern and the existence of toxicological effects only at high dose levels in experimental animals minimizes any concern for exposure to the very low doses that may be present as a result of the proposed uses." *includes this. π*

SECTION D - AGGREGATE EXPOSURE

1) Dietary Exposure:

Existing -

Hydrogen peroxide has recently been registered for food uses as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices, and has been issued an exemption from the requirement of a tolerance for residues up to 120 ppm, when used as an antimicrobial agent on those agricultural crops (Ecolab Inc., 40 CFR Part 180.1197). Other existing regulations relating to hydrogen peroxide are as follows:

- GRAS when used on milk intended for use in cheese making (maximum treatment level of 0.05%), on whey during preparation of modified whey by electrodialysis methods (maximum treatment level of 0.04%), dried eggs, dried egg whites, dried egg yolks, tripe, beef feet, herring, wine, starch (maximum treatment level of 0.15%), instant tea, corn syrup (maximum treatment level of 0.15%), wine vinegar, and emulsifiers containing fatty acid esters (maximum treatment level of 1.25%). [21 CFR Part 184.1366]
- Approved for use as a sanitizing solution for use on food processing equipment and utensils, and on dairy processing equipment. Also, approved for use in sterilizing polymeric food-contact surfaces. [21 CFR Part 178.1010]
- Approved for use in washing or to assist in the lye peeling of fruits and vegetables. [21 CFR Part 173.315]

Petition -

Dietary exposure from use of hydrogen peroxide, as proposed, is minimal. Hydrogen peroxide reacts rapidly on contact with surfaces such as food and degrades into oxygen and water, neither of which are of toxicological concern.

2) Drinking Water Exposure:

The proposed use may result in the transfer of minor amounts of residues to potential drinking water sources. However, there is no concern for exposure due to the fact that the residues of hydrogen peroxide are oxygen and water, neither of which are of toxicological concern. As stated in the existing exemption, "...the EPA Office of Water indicates that when used for potable water disinfection, no residues of hydrogen peroxide are present by the time the water is pumped through a distribution system." [40 CFR part 180.1197]

This is not true

3) Non-Dietary Exposure:

Existing -

Hydrogen peroxide is currently registered as a pesticide, with active ingredient concentrations ranging from 5.8% to 50%, for the following uses:

- Agricultural premises and equipment
- Ornamental plants (flowers, bedding plants, shrubs and trees) and turf
- Food handling / storage establishment premises and equipment
- Commercial, institutional and industrial premises and equipment
- Residential and public access premises
- Medical premises and equipment
- Materials preservation
- Industrial processes and water systems

Hydrogen peroxide is currently approved for the following medicinal uses:

- Sanitization of cuts, scrapes and burns to humans
- Oral sanitization mouthwash
- Toothpaste
- General cleansing/sanitization of surgical areas of the body after operations

Petition -

The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are commercial, agricultural and horticultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

Person Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in commercial, agricultural and horticultural settings. As stated in Section C - Toxicological Profile, for additional protection BioSafe System's product labels specify precautionary statements and PPE based on toxicity categories for a 50% active ingredient concentration product; almost double the maximum concentration of BioSafe products (27%).

SECTION E - CUMULATIVE EFFECTS

It is not expected that, when used as proposed, hydrogen peroxide would result in residues that would remain in human food items. Hydrogen peroxide reacts on contact and degrades rapidly into compounds that are not of toxicological concern.

SECTION F - SAFETY DETERMINATION

1) General US Population:

In the established exemption from the requirement of a tolerance EPA "...has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or intermediate-term exposures from the proposed food contact uses of hydrogen peroxide" [40 CFR Part 180.1197]. Hydrogen peroxide degrades rapidly on contact into residues that are not of toxicological concern. Chronic risk from dietary exposure is not anticipated. Residues of hydrogen peroxide are not expected on agricultural commodities, and therefore, exposure to the general US population, from the proposed uses, is not anticipated.

2) Infants and Children:

As mentioned above, residues of hydrogen peroxide are not expected on agricultural commodities. Hydrogen peroxide degrades rapidly on contact into residues that are not of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to hydrogen peroxide from the proposed uses.

SECTION G - EXISTING TOLERANCES

US EPA Tolerance -

40 CFR Part 180.1197 - Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices.

International -

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

SECTION H - INFORMATION ON ENDOCRINE EFFECTS

To date there is no evidence to suggest that hydrogen peroxide functions in a manner similar to any known hormone or that it acts as an endocrine disrupter.

his document will publish in the
FEDERAL REGISTER 9/23/98
Approximately 24 hours after
publication, page numbers are
available by calling the Federal
Register Staff (FRS) at 202-260-2253
Please refer to the FRL number at
the top of the first page or the
number at the bottom left corner
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available in the FRS Office.

John A. Richards, Director
Federal Register Staff

ANNE BALL 7511W

ENVIRONMENTAL PROTECTION AGENCY

[PF-834; FRL-6028-4]

Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF-834, must be received on or before (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Anne S. Ball, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 5th. FL, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308-8717; e-mail: ball.anne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the

98P-1636

elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-834] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF-834] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 8, 1998

Kathleen D. Knox

Kathleen D. Knox, Acting

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Alex M. Allen
 Certified to be a true
 copy of the original.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Biosafe Systems

PP 8F4996

EPA has received a pesticide petition 8F4996 from Biosafe Systems, 45 E. Woodthrush Trail, East Medford, NJ 08055, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide hydrogen peroxide in or on all food commodities.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Biosafe Systems has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Biosafe Systems and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Product Name and Proposed Use Practices

ZeroTol Broad Spectrum Algicide/Fungicide; Oxidate Broad Spectrum Algicide/Fungicide. Biosafe has already registered ZeroTol for use as an algicide, bactericide and fungicide to control plant pathogenic diseases on ornamentals and turf. Biosafe intends to pursue the same use pattern for Oxidate (bactericide, fungicide) as a plant dip, soil drench and foliar spray on food crops in greenhouse and agricultural use sites (such as nurseries). Both products contain 27% hydrogen peroxide by weight as the active ingredient. The food crops are as follows: apples, bananas, beans, broccoli, cabbage, cauliflower, cherries, cucurbits, filberts, grapes, nectarines, onions, peaches, peppers, plums, potatoes (including seed potatoes), prunes, and tomatoes.

B. Product Identity/Chemistry

1. *Identity of the pesticide.* Zerotol and Oxidate Algicide/Fungicide both contain 27% hydrogen peroxide as the active ingredient which is a colorless, moderately pungent liquid and is soluble in water. The pH is 1.05 at 25 °C, and it is non-flammable and non-explosive. In storage it is unstable at 50 °C at 30 days, is moderately corrosive and its viscosity is 0.78 cS at 22 °C. The boiling point is 100 °C and the specific gravity is 1.091 at 22 °C.

2. *Magnitude of residue at the time of harvest.* Biosafe believes that hydrogen peroxide reacts on contact with a surface on which it is applied, and rapidly degrades to oxygen and water, neither of which are of toxicological

concern. Biosafe quotes a **Federal Register** notice of May 6, 1998 (63 FR 24949) (FRL 5789-2) in which the EPA established an exemption from the requirement of a tolerance for residues of the antimicrobial pesticide hydrogen peroxide up to 120 ppm, in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices. "Therefore, the lack of residues of toxicological concern and the existence of toxicological effects only at high dose levels (HDL) in experimental animals minimizes any concern for exposure to the very low doses that may be present as a result of the proposed uses."

3. A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed. Biosafe has quoted the same **Federal Register** notice of May 6, 1998 as follows: "Hydrogen peroxide is highly reactive and short lived because of the inherent instability of the peroxide bond (i.e., the O-O bond). Agitation or contact with rough surfaces, sunlight, organics and metals accelerates decomposition. The instability of hydrogen peroxide to exist as itself, along with detoxifying enzymes found in cells (e.g. catalase, glutathione peroxidase), makes it very difficult to find any residues in or on foods (at proposed use levels) by conventional analytical methods."

C. Mammalian Toxicological Profile

BioSafe Systems proposes products containing 27% hydrogen peroxide by weight. In all cases the product is diluted with water at a rate of 1:50, 1:100 or 1:300, which results in a concentration of 0.25% to 1.50% hydrogen peroxide in the product that is applied. BioSafe Systems has cited open literature with respect to toxicity data which shows that hydrogen peroxide is toxic at high levels; that at a 1.5% concentration it has no impact on human skin, eyes or respiratory system; that the concentrate has a pH of 1.05 and thus has been categorized in Toxicity Category I for skin and eye irritation; that for the oral route of exposure, a concentration of 0.5% hydrogen peroxide was determined not to present a possible adverse effect due to the fact that hydrogen peroxide at concentrations of 0.04 and 0.05% has been classified as GRAS by FDA and USDA for use as a food additive, toothpaste or mouthwash. Biosafe summarized open literature pertaining to toxicology as follows:

Solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} > 5,000$ milligram/kilogram (mg/kg) in rats (Toxicity Category III), an acute dermal $LD_{50} > 10,000$ mg/kg in rabbits (Toxicity Category IV), and an inhalation LC_{50} of 4 mg/l (Toxicity Category IV). Such solutions are mild irritants to rabbit skin and cause severe, irreversible corneal injury in half of the exposed rabbits (Toxicity Category I).

Solutions containing 50% hydrogen peroxide have an acute oral $LD_{50} > 500$ mg/kg in rats (Toxicity Category II) and an acute dermal $LD_{50} > 1,000$ mg/kg in rabbits (Toxicity Category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2,000 ppm). Solutions containing 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (Toxicity Category I).

Ann
~~0.125 = 0.54%~~
 $\frac{27}{50} = 0.54\%$
 $\frac{27}{100} = 0.27\%$
 $\frac{27}{300} = 0.09\%$
 $0.09 \rightarrow 0.54\%$

D. Aggregate Exposure

1. *Dietary exposure—Food.* BioSafe has asserted that dietary exposure from use of hydrogen peroxide, as proposed is minimal since hydrogen peroxide reacts rapidly on contact with surfaces such as food and degrades into oxygen and water, neither of which are of toxicological concern.

2. *Drinking water.* BioSafe states that the proposed use may result in the transfer of minor amounts of residues to potential drinking water sources, however there is no concern for exposure due to the fact that the residues of hydrogen peroxide are oxygen and water, neither of which are of toxicological concern. Biosafe quotes the existing exemption'' the EPA Office of Water indicates that when used for potable disinfection, no residues of hydrogen peroxide are present by the time the water is pumped through a distribution system.'' 40 CFR 180.1197.

3. *Non-dietary exposure.* BioSafe states that the potential for non-dietary exposure to the general population including infants and children is unlikely as the proposed use sites are commercial, agricultural and horticultural settings and that non-dietary exposures would not be expected pose any quantifiable risk due to lack of residues of toxicological concern.

E. Cumulative Exposure

BioSafe states that it is not expected that, when used as proposed, hydrogen peroxide would result in residues that would remain in human food items since hydrogen peroxide reacts on contact and degrades rapidly into compounds that are not of toxicological concern.

F. Safety Determination

1. *U.S. population.* Biosafe quotes from the established exemption from the requirement of a tolerance that EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or intermediate-term exposures from the proposed food contact uses of hydrogen peroxide''. BioSafe states that since hydrogen peroxide degrades rapidly on contact into residues that are not of toxicological concern, chronic risk from dietary exposure is not anticipated and since residues of hydrogen peroxide are not expected on agricultural commodities, exposure to the general U.S. population from the proposed uses is not anticipated.

2. *Infants and children.* BioSafe states that, as mentioned above, residues of hydrogen peroxide are not expected on agricultural commodities and that hydrogen peroxide degrades rapidly on contact into residues that are of no toxicological concern and that there is a reasonable certainty of no harm for infants and children from exposure to hydrogen peroxide from the proposed uses.

G. Effects on the Immune and Endocrine Systems

BioSafe has cited open literature in that weak direct mutagenicity responses were seen for hydrogen peroxide in Ames tests with *Salmonella typhimurium* strains TA97, TA98, TA102, and TA1537 in a 20 minute preincubation test and in a liquid incubation modification using strain TA1537. Biosafe states that there

is additional information regarding immunotoxicity, developmental toxicity and chronic toxicity in the open literature.

H. Existing Tolerances

An exemption from the requirement of a tolerance has been established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices (40 CFR 180.1197).

I. International Tolerances

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

[FR Doc. 98-????? Filed ??-??-98; 8:45 am]

BILLING CODE 6560-50-F

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REVIEWER: ANNE BELL

(ASSIGNED BY: JOBLAD)

EPA REG./FILE SYMBOL 8F4996
70299

ACTION CODE 230
232

SUBMISSION BARCODE S546042

Date on Application 6-24-98

EPA Received Date 6-25-98

PM Received Date 7-7-98

Assigned in PRAT YES ☒ NO ☐

Completed by: S. Diana Hudson

Date 7/22/98

*Petition for
Exemption*

FINAL ACTION

Response Code _____

Response Date: / /

MOS: _____ (1) Cite-All

_____ (4) Not Applicable

_____ (8) Selective

CRP: Yes _____ No _____

Restricted Use: Yes _____ No _____

Manufacturing Use: Yes _____ No _____

Exclusive Use: Yes _____ No _____

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REVIEWER: DAVE BALE

(ASSIGNED BY: S. J. BEND)

EPA REG./FILE SYMBOL 8F4996
2299-1

ACTION CODE 230

SUBMISSION BARCODE 5545621

Date on Application 6-24-98

EPA Received Date 6-25-98

PM Received Date 7-14-98

Assigned in PRAT YES ☒

NO ☐

Completed by: S. Diana Hudson

Date 7-14-98

Petition

FINAL ACTION

Response Code _____

Response Date: / /

MOS: _____ (1) Cite-All

_____ (4) Not Applicable

_____ (8) Selective

CRP: Yes _____ No _____

Restricted Use: Yes _____ No _____

Manufacturing Use: Yes _____ No _____

Exclusive Use: Yes _____ No _____

FRONT END PROCESSING FORM TO FILE ROOM

DATE 6-30-98

FILE NUMBER 8F4996

☒ No Data - File Room "Make Ready for R. Sjoberg"
(PM or individual)

☒ Data - File Room "Assign Jacket to Shelf"

☐ Rejected - File Room "Assign Jacket to Rejected Shelf"

2

6-30-98

United States Environmental Protection Agency
Office of Pesticide Programs
Information Resources and Services Division
Information Services Branch



ADMINISTRATIVE NO(S).: 8F4996

PM: 91 Roy ~~Sto~~ Sjoberg

CHEMICAL NO.: _____

The jacket for this action can be
requested through the JACKETS system.

8F4996



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Roy Sjoblad
Chief, Biochemicals Branch
Biopesticides and Pollution Prevention Division (7511W)
Office of Pesticide Programs
1921 Jefferson Davis Highway
Arlington, VA 22202

June 24, 1998

RE: Petition for an exemption from the requirement of a tolerance for residues of products containing the active ingredient HYDROGEN PEROXIDE, in and on all raw agricultural commodities, when applied as a pesticide to growing agricultural crops.

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Mr. Sjoblad:

With this letter Technology Sciences Group, on behalf of BioSafe Systems (EPA Company No. 70299), hereby submits a petition for the following:

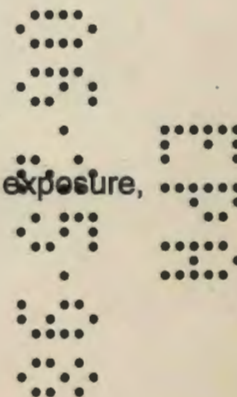
An exemption from the requirement of a tolerance for residues of products containing the active ingredient **hydrogen peroxide**, in and on all raw agricultural commodities, when used as a pesticide on growing agricultural crops, in accordance with 40 CFR Part 180 and pursuant to Section 408(d)(1) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

In support of this petition, attached you will find the following information, submitted in duplicate:

- A. Summary of product chemistry;
- B. Proposed use practice;
- C. Toxicological profile;
- D. Aggregate exposure, including information on dietary exposure, drinking water exposure and non-dietary exposure;
- E. Cumulative effects;



E-mail tsg@tsgusa.com

<http://www.tsgusa.com>



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Page 2
June 24, 1998

- F. Safety determination, including information on the U.S. general population, and infants and children;
- G. Existing tolerances;
- H. Information on endocrine effects.


Information listed above has already been reviewed by EPA and most of the summaries provided reflect the findings of Agency reviewers. The petitioner agrees that the enclosed information may be published as part of the notice of filing of the petition, to be published under Section 408(d)(1), and as proposed for final regulation.

 SAN FRANCISCO
2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Please note on April 30, 1998 an exemption from the requirement of a tolerance was established for hydrogen peroxide, up to 120 ppm, in or on raw agricultural commodities and in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices (40 CFR Part 180.1197). The established exemption specifies the use of hydrogen peroxide as an antimicrobial agent. BioSafe Systems proposes other uses of hydrogen peroxide, specifically as an algicide, fungicide, bactericide and insecticide, and believes that a new exemption is required to include those uses.

With this letter we are also requesting a **waiver of the fee for filing a petition** for an exemption from the requirement of a tolerance, for the following reasons:

- 1) Hydrogen peroxide is an already registered active ingredient with an established tolerance exemption for similar uses. The active ingredient reacts on contact and the degradation products (oxygen and water) are not of toxicological concern. Hydrogen peroxide does not pose any potential for unreasonable adverse effects to human health;

 SACRAMENTO
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<http://www.tsgusa.com>



WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Page 3
June 24, 1998

- 2) The fee for filing a petition for an exemption from the requirement of a tolerance would pose unreasonable hardship on the registrant, BioSafe Systems. BioSafe is a small, family-owned company that currently maintains one EPA registered product (hydrogen peroxide for use as an algicide / fungicide on ornamental plants and turf - EPA Reg. No. 70299-1). At this time the fee would present undue financial strain on the company.

We have submitted the appropriate fee (\$1,550) for filing a waiver request to EPA Headquarters Accounting Operations Branch, Pittsburgh, PA, on this date, with a copy of this letter included for reference.

Should you have any questions or comments on this petition please contact me directly.

Sincerely,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems
(202) 828-8964

SAN FRANCISCO

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

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SACRAMENTO

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COPY



WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

<sent via Certified Mail, article number P 175 814 700>

Environmental Protection Agency
Headquarters Accounting Operations Branch
Office of Pesticide Programs (Tolerance Fees)
P.O. Box 360277M
Pittsburgh, PA 15251

June 24, 1998

RE: Tolerance Petition Fees

SAN FRANCISCO

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

Dear HQ Accounting Operations Branch:

With this letter Technology Sciences Group, on behalf of BioSafe Systems (EPA Company No. 70299), hereby submits the following in support of a petition for an exemption from the requirement of a tolerance:

- 1) Check for \$1,550 - fee for requesting a waiver of the fees for filing a petition for an exemption from the requirement of a tolerance.
- 2) Copy of the cover letter submitted with the petition; includes rational for waiver of the filing fee.

Should you have any questions or comments, please contact me directly at (202) 828-8964.

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Sincerely,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems

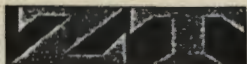
SECTION B - PROPOSED USE PRACTICE

BioSafe Systems has already registered hydrogen peroxide (27% active ingredient concentration by weight) for use as an algicide, bactericide and fungicide to control plant pathogenic diseases on ornamentals and turf (ZeroTol™ Broad Spectrum Algicide / Fungicide, EPA Reg. No. 70299-1). BioSafe intends to pursue the same use pattern (bactericide, fungicide) as a plant dip, soil drench and foliar spray on the following food crops in greenhouse and agricultural use sites (such as nurseries):

- Beans
- Broccoli
- Cauliflower
- Cabbage
- Cucurbits
- Onions
- Peppers
- Potatoes (including seed potatoes)
- Tomatoes
- Apples
- Filberts
- Bananas
- Grapes
- Peaches
- Plums
- Cherries
- Nectarines
- Prunes

In addition, at a later date BioSafe intends to pursue an application for registration of hydrogen peroxide for use as an insecticide to control greenhouse pests, such as fungus gnats, whiteflies, thrips, aphids, mealy bugs and scale, on ornamental and food crops.

A proposed food use label is found immediately following this page.



Oxide™



Broad Spectrum Bactericide / Fungicide

DRAFT

- * Preventative treatment for growing plants, fruits, nuts and vegetables.
- * A treatment for the prevention and control of plant pathogenic diseases in the field, commercial greenhouses, garden centers, landscapes, nurseries and interiorscapes.

FOR AGRICULTURAL AND COMMERCIAL USE ONLY

ACTIVE INGREDIENT:

Hydrogen Peroxide..... 27%

INERT INGREDIENTS:..... 73%

TOTAL:..... 100%

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand this label, find someone to explain it to you in detail.)

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get immediate medical attention.

IF ON SKIN: Remove contaminated clothing and wash affected areas with plenty of soap and water. Get immediate medical attention.

IF SWALLOWED: Call a physician or poison control center immediately. Drink large quantities of water. Do not induce vomiting. Avoid alcohol. Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED: Remove victim to fresh air. Get immediate medical attention.

See side panel for additional precautionary statements.

Sold by: BioSafe Systems, 45 E. Woodthrush Trail, Medford, NJ 08055

EPA Registration No. 70299-

EPA Establishment No. 68660-TX-01

Net Contents: 2.5 gallons

Oxide Broad Spectrum Bactericide/Fungicide
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Hydrogen Peroxide Tolerance Exemption

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CORROSIVE: Concentrate causes irreversible eye damage. Concentrate may be fatal if swallowed. Concentrate causes skin irritation or temporary discoloration on exposed skin. Do not breathe vapor of concentrate. Do not get concentrate in eyes, on skin or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

When handling concentrate wear protective eyewear (goggles or face shield) and rubber gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water.

USER SAFETY RECOMMENDATIONS

Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

FOR TERRESTRIAL USES. Keep out of lakes, ponds and streams. This pesticide is toxic to birds and fish. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wash waters.

This product is highly toxic to bees and other beneficial insects exposed to direct contact on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. Do not apply this product or allow it to drift to crops where beneficials are part of an Integrated Pest Management strategy.

PHYSICAL AND CHEMICAL HAZARDS

Strong oxidizing agent. **Corrosive.** Do not use in concentrated form. Mix only with water in accordance with label instructions. Never bring concentrate in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about Personal Protective Equipment (PPE) and Restricted-Entry Interval (REI). The requirements in this box only apply to the uses of this product that are covered by the Worker Protection Standard.

There is a restricted entry of zero (0) hours for this product.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: long-sleeved shirt, long pants, and shoes plus socks.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinses (or equivalent). Then offer for recycling or dispose in a sanitary landfill, or incineration, if allowed by state and local authorities by burning, stay out of smoke.

DIRECTIONS FOR USE:

- * Oxidate™ works best when diluted with water containing low levels of organic or inorganic materials, and with water having a neutral pH. Thoroughly rinse out tank with water before mixing concentrate. Oxidate™ will readily mix with clean, neutral water and does not require agitation.
- * Oxidate™ should not be combined or mixed with any other pesticide or fertilizer.
- * Oxidate™ is formulated with a minimal amount of surfactant for plants having waxy or hairy surfaces. Additional surfactant may be added at a rate of 1 to 2 ounces per gallon, if needed.

Oxidate™ works by surface contact with the plants and materials being treated. It is important to ensure that all surfaces are thoroughly wetted. Oxidate™ does not produce any visible residue, distinct odor or deleterious effects to plants when used in accordance with label directions. Do not use at higher than recommended dilution rates as leaf burn may result.

Oxidate Broad Spectrum Bactericide/Fungicide

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Do not apply this product through any irrigation system unless directed by the label; refer to Chemigation Directions for Use.

Use Rates and Directions:

Pre-Plant Dip Treatment -

Use Oxidate™ for the control of damping-off, root disease and stem rot disease caused by *Pythium*, *Phytophthora*, *Rhizoctonia*, *Fusarium* or *Thielaviopsis*, on seeds, seedlings, bulbs, or cuttings.

- 1) Mix 64 fl. oz. per 50 gallons of water.
- 2) Immerse plants or cuttings; remove and allow to drain. Do not rinse.

Soil Drench -

Oxidate™ is effective for the control of soil borne plant diseases such as *Pythium*, *Phytophthora*, *Rhizoctonia*, *Thielaviopsis* or *Fusarium*. Use as a soil drench at the time of seeding or transplanting, as well as a periodic drench throughout the plant's life. Oxidate™ can also be used on potting soil and growing mediums prior to planting.

- 1) Mix 2½ fl. oz. Oxidate™ per gallon of clean water.
- 2) Apply to soil or growing media to the point of saturation.
- 3) Wait fifteen minutes before planting or watering.

Foliar Spray Treatments for field grown crops, crops grown in commercial greenhouses or crops grown in other similar sites -

Oxidate™ works immediately on contact with any plant surface for control. Good coverage and wetting of the foliage is necessary.

Crops	Disease	Dilution Rate Application Rate	Directions
Beans	Anthracnose Downy Mildew Powdery Mildew Rust	1:100 – 1:300 [40–128 oz. of concentrate per 100 gallons of water.]	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1:100 [50 – 100 gallons of spray solution per acre. 128 oz. of concentrate per 100 gallons of water.]	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Broccoli Cauliflower Cabbage	Alternaria Leaf Spot Downy Mildew Powdery Mildew	1:100 – 1:300	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest.
		1:100	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

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Crops	Disease	Dilution Rate	Directions
Cucurbits	Alternaria Anthracnose Downy Mildew Powdery Mildew Pythium Rot	1:100 – 1:300 1: 100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Onions	Botrytis Downy Mildew Powdery Mildew	1:100 – 1:300 1: 100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Peppers	Anthracnose Phytophthora Blight Powdery Mildew	1:100 – 1:300 1: 100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Potatoes	Early Blight Late Blight	1:100 – 1:300 1: 100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Seed Potatoes	Fusarium	1: 50	Dip whole or cut tubers into tank of working solution. Let soak for a period of five minutes before removing seed pieces.
Tomatoes	Anthracnose Cladosporium Mold Early Blight Late Blight Powdery Mildew	1:100 – 1:300 1: 100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Apples	Rusts Scab Powdery Mildew	1:100 1: 100	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

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Crops	Disease	Dilution Rate	Directions
Filberts	Eastern Filbert Blight Bacterial Blight	1:100 1:100	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Bananas	Sigatoka	1:100 – 1:300 1:100	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Grapes	Black Rot Downy Mildew Powdery Mildew	1:100 – 1:300 1:100	Preventive: Begin when shoots are small. Apply first three treatments at 1:100, for 5 day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5 day interval spray cycle until harvest. Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
Stone Fruits Peaches Plums Cherries Nectarines Prunes	Downy Mildew Powdery Mildew Brown Rot	1:100	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

Chemigation Directions for Use

General Requirements:

- 1) Apply this product only through a sprinkler including a center pivot, lateral move, end tow, side wheel roll, traveler, solid set, hand move, flood basin or drip trickle irrigation system. Do not apply this product through any other type of irrigation system.
- 2) Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.
- 3) Ensure that the irrigation system used is properly calibrated and if you have questions, call the state extension service or the equipment manufacturer.
- 4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless proper safety devices for public water systems are in place. Read label for instructions.
- 5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

(Chemical Directions for Use, cont.)

Specific Requirements:

- 1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
- 2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top of the overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- 3) The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of liquid back towards the injector.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid, operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being drawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump, or equivalent, effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Application Instructions:

- 1) Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and entire injector system. Flush with clean water. Failure to provide a clean tank, void of scale or residues may cause product to lose effectiveness or strength.
- 2) Determine the treatment rates as indicated in the directions for use and make proper dilutions.
- 3) Prepare a solution in the chemical tank by filling the tank with the required water and then adding product as required. The product will immediately go into suspension without any required agitation.
- 4) Oxidate should not be applied in conjunction with any other pesticides or fertilizers; this may cause reduced performance of the product and should be avoided.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, method of application, weather, watering practices, nature of soil, potting medium, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith, NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

SECTION C - TOXICOLOGICAL PROFILE

BioSafe Systems proposes products containing 27% hydrogen peroxide, by weight. In all cases the product is diluted with water, at a rate of 1:50, 1:100 or 1:300, which results in a concentration of 0.25% to 1.50% hydrogen peroxide in the product that is applied.

As hydrogen peroxide is a well known, well-tested active ingredient, BioSafe Systems has relied on published literature to fulfill toxicity data requirements. Open literature information submitted indicates that hydrogen peroxide is toxic at high levels, but that a 1.5% concentration it has no impact on human skin, eyes or respiratory systems. As the BioSafe products (the concentrate before dilution with water) have a pH of 1.05, they are rated Toxicity Category I for skin and eye irritation, and carry the appropriate label warnings and personal protective equipment for that category. For the oral route of exposure, a concentration of 0.5% hydrogen peroxide was determined not to present a potential adverse effect; due to the fact that hydrogen peroxide, at concentrations of 0.04 and 0.05%, has been classified as GRAS by FDA (184.1366) and USDA for use as a food additive, toothpaste or mouthwash. Per EPA request, for maximum protection BioSafe product labels for agricultural use have precautionary statements based on toxicity study results reported for a 50% concentration hydrogen peroxide solution, as noted below.

A summary of open literature previously submitted is as follows:

Solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ mg/kg in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 mg/l (toxicity category IV). Such solutions are mild irritants to rabbit skin and cause severe, irreversible corneal injury in half of the exposed rabbits (toxicity category I).

Solutions containing 50% hydrogen peroxide have an acute oral $LD_{50} \geq 500$ mg/kg in rats (toxicity category II) and an acute dermal $LD_{50} \geq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} is 4 mg/l (2000 ppm). Solutions containing 50% hydrogen peroxide are also extremely irritating (corrosive) to rabbit eyes (toxicity category I). Weak direct mutagenicity responses were seen for hydrogen peroxide in Ames tests with *Salmonella typhimurium* strains TA97, TA98, TA102 and TA1537 in a 20 minute preincubation test and in a liquid incubation modification using strain TA1537.

Additional information regarding immunotoxicity, development toxicity and chronic toxicity (at various concentrations of hydrogen peroxide) was also submitted from the open literature. For more information refer to **MRID No. 441160-05**, Review of Hydrogen Peroxide Toxicity.

Further information can also be referenced from the established exemption from the requirement of a tolerance of hydrogen peroxide when used as an antimicrobial agent, which states the following:

(Excerpts of Federal Register from May 6, 1998 [Volume 63, Number 87, Pages 24955 - 24963])

"Hydrogen peroxide is highly reactive and short lived because of the inherent instability of the peroxide bond (i.e., the O-O bond). Agitation or contact with rough surfaces, sunlight, organics and metals accelerates decomposition. The instability of hydrogen peroxide to exist as itself, along with detoxifying enzymes found in cells (e.g., catalase, glutathione peroxidase), makes it very difficult to find any residues of hydrogen peroxide in or on foods (at proposed use levels), by conventional analytical methods."

"Residues are not of toxicological concern because hydrogen peroxide decomposes rapidly into oxygen and water. The Agency has no toxicological concern with oxygen and water."

"Therefore, the lack of residues of toxicological concern and the existence of toxicological effects only at high dose levels in experimental animals minimizes any concern for exposure to the very low doses that may be present as a result of the proposed uses."

SECTION D - AGGREGATE EXPOSURE

1) Dietary Exposure:

Existing -

Hydrogen peroxide has recently been registered for food uses as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices, and has been issued an exemption from the requirement of a tolerance for residues up to 120 ppm, when used as an antimicrobial agent on those agricultural crops (Ecolab Inc., 40 CFR Part 180.1197). Other existing regulations relating to hydrogen peroxide are as follows:

- GRAS when used on milk intended for use in cheese making (maximum treatment level of 0.05%), on whey during preparation of modified whey by electrodialysis methods (maximum treatment level of 0.04%), dried eggs, dried egg whites, dried egg yolks, tripe, beef feet, herring, wine, starch (maximum treatment level of 0.15%), instant tea, corn syrup (maximum treatment level of 0.15%), wine vinegar, and emulsifiers containing fatty acid esters (maximum treatment level of 1.25%). [21 CFR Part 184.1366]
- Approved for use as a sanitizing solution for use on food processing equipment and utensils, and on dairy processing equipment. Also, approved for use in sterilizing polymeric food-contact surfaces. [21 CFR Part 178.1010]
- Approved for use in washing or to assist in the lye peeling of fruits and vegetables. [21 CFR Part 173.315]

Petition -

Dietary exposure from use of hydrogen peroxide, as proposed, is minimal. Hydrogen peroxide reacts rapidly on contact with surfaces such as food and degrades into oxygen and water, neither of which are of toxicological concern.

2) Drinking Water Exposure:

The proposed use may result in the transfer of minor amounts of residues to potential drinking water sources. However, there is no concern for exposure due to the fact that the residues of hydrogen peroxide are oxygen and water, neither of which are of toxicological concern. As stated in the existing exemption, "...the EPA Office of Water indicates that when used for potable water disinfection, no residues of hydrogen peroxide are present by the time the water is pumped through a distribution system." [40 CFR part 180.1197]

3) Non-Dietary Exposure:

Existing -

Hydrogen peroxide is currently registered as a pesticide, with active ingredient concentrations ranging from 5.8% to 50%, for the following uses:

- Agricultural premises and equipment
- Ornamental plants (flowers, bedding plants, shrubs and trees) and turf
- Food handling / storage establishment premises and equipment
- Commercial, institutional and industrial premises and equipment
- Residential and public access premises
- Medical premises and equipment
- Materials preservation
- Industrial processes and water systems

Hydrogen peroxide is currently approved for the following medicinal uses:

- Sanitization of cuts, scrapes and burns to humans
- Oral sanitization mouthwash
- Toothpaste
- General cleansing/sanitization of surgical areas of the body after operations

Petition -

The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are commercial, agricultural and horticultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

Person Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in commercial, agricultural and horticultural settings. As stated in Section C - Toxicological Profile, for additional protection BioSafe System's product labels specify precautionary statements and PPE based on toxicity categories for a 50% active ingredient concentration product; almost double the maximum concentration of BioSafe products (27%).

SECTION E - CUMULATIVE EFFECTS

It is not expected that, when used as proposed, hydrogen peroxide would result in residues that would remain in human food items. Hydrogen peroxide reacts on contact and degrades rapidly into compounds that are not of toxicological concern.

SECTION F - SAFETY DETERMINATION

1) General US Population:

In the established exemption from the requirement of a tolerance EPA "...has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short-term or intermediate-term exposures from the proposed food contact uses of hydrogen peroxide" [40 CFR Part 180.1197]. Hydrogen peroxide degrades rapidly on contact into residues that are not of toxicological concern. Chronic risk from dietary exposure is not anticipated. Residues of hydrogen peroxide are not expected on agricultural commodities, and therefore, exposure to the general US population, from the proposed uses, is not anticipated.

2) Infants and Children:

As mentioned above, residues of hydrogen peroxide are not expected on agricultural commodities. Hydrogen peroxide degrades rapidly on contact into residues that are not of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to hydrogen peroxide from the proposed uses.

SECTION G - EXISTING TOLERANCES

US EPA Tolerance -

40 CFR Part 180.1197 - Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs and spices.

International -

There is no Codex Alimentarium Commission Maximum Residue Level (MRL) for hydrogen peroxide.

SECTION H - INFORMATION ON ENDOCRINE EFFECTS

To date there is no evidence to suggest that hydrogen peroxide functions in a manner similar to any known hormone or that it acts as an endocrine disrupter.